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Review

Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model

A Faulkner LG Kennedy K Baxter J Donovan M Wilkinson G Bevan



Health Technology Assessment NHS R&D HTA Programme

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List of abbreviations

| CI | confidence interval [*] |
|-------------|--|
| GP | general practitioner |
| HA | hydroxyapatite |
| HBF | heterotopic bone formation [*] |
| HMHDPE | high molecular weight, high density polyethylene * |
| MACTAR | McMaster–Toronto Arthritis Patient Function Preference Questionnaire [*] |
| RCT | randomised controlled trial |
| RSA | roentgen stereophotogrammetry * |
| SEM | standard error of the mean [*] |
| SIFT | Service Increment for Teaching |
| SSTRR | Standard System of Terminology for Reporting Results [*] |
| THR | total hip replacement |
| WOMAC | Western Ontario and McMaster Universities Arthritis Index [*] |
| * Used only | in appendix |
| | ations of the names of specific prostheses are given prostheses designs |

Prostheses designs

The following prostheses or prosthesis components are discussed in the publications covered by this review and, where possible, the name of the supplier/manufacturer of the prosthesis is given in parentheses. However, in some cases, the supplier/manufacturer was not identified in the original published document and the names of these prostheses are marked with an asterisk (*).

ABG (Howmedica) Accu-Path* ACS (DePuy) AlloPro (Intermedics Orthopedics) AML (DePuy) AML Porcoat (DePuy) Anatomic Medullary Locking - see AML Anatomic Porous Replacement - see APR **APR** (Intermedics Orthopedics) ARC (Howmedica) Arthrophor (Joint Medical Products) ATS (Howmedica) Aufranc-Turner (Howmedica/Zimmer) Autophor (Smith and Nephew) Balgrist (Germany)* BIAS (Zimmer) Bichat (Howmedica) Bimetric* Biofit (Smith & Nephew) **Biological Ingrowth** Anatomic System – see BIAS Boneloc[®] (cement) Brunswick* Buck 32* Butel® (Smith & Nephew/Richards) CAD (Howmedica) Ceraver Osteal - see Osteal (Aluminia) Charnley (DePuy) **Charnley Low Friction** Arthroplasty - the name given to the original Charnley design Charnley-Müller (DePuy)

CDH (Howmedica) Christiansen (Delrin, Dupont) CLS (Protek) $DF 80^*$ Dual Lock (DePuy, Zimmer or Protek) Duraloc (DePuy) Elite (DePuy) Engh-Anderson (DePuy) **Exeter Polished** (Howmedica) Femora^{*} Freeman (Corin Medical) Furlong (JRI) Griss (Sulzer AG) Harris (Howmedica) Harris Design 2 (Howmedica) Harris-Galante (Zimmer) Harris Precoat (Zimmer) HD-2 - see Harris Design 2 Honnart Patel-Garches^{*} Howse* HP-Garches - see Honnart Patel-Garches HS9P* ICLH* Indiana Conservative (DePuy) Intermedic (Intermedics) IOWA (Zimmer) **Kirschner Anatomic** (Kirschner) Kirschner Murray Welch (Kirschner) Link V (Link America) Lubinus SP (Waldemar Link)

 LD^* LMT^* Lord Madreporic* Mallory Head (Biomet) Marburg* McKee-Farrar (Howmedica) Mecring (Mecron Medical) Mecron (Mecron Medical) MHP - see Mallory Head Miami Orthopedic Surgical Club - see MOSC Morscher^{*} MOSC (Biomet) Müller (Straight Stem) (Protek AG) **Omnifit** (Osteonics) Optifix* Osteal aluminia (Ceraver) P-2 – see Protasul 2 P-10 - see Protasul 10 PCA[®] (Howmedica) Pennsylvania Total Hip Porous Coated Anatomic - see PCA® Precoat – see Harris Precoat Profile (DePuy) Protasul 2 (Sulzer Brothers) Protasul 10 (Sulzer Brothers) Richard (Richards) Ring (Zimmer) RM (R Mathys Company) Romanus (Biomet) Scanhip (Mitab AB) SixTi/28 (Zimmer)

SLF (Corin Medical) Spectron/Biofit (Richards) Spectron/ITH (Richards) Spectron Lubinus see SP Lubinus Spectron EF (Smith & Nephew Richards) SP Lubinus (Waldemar Link) SRN-REV - see S-ROM Anderson S-ROM Anderson (Joint Medical Products) S-ROM Super (Joint Medical Products) Stackhouse* Stanmore (Biomet) STH-2 (Zimmer) T-28 (Zimmer) Taperloc (Biomet) TARA (DePuy) Tharies* TiBac (Zimmer) Ti-Fit (Smith & Nephew Richards) Titan (Landos) **Total Articular Resurfacing Arthroplasty** - see TARA **TR-28*** Trapezoidal-28 – see T-28 Triad (Johnson & Johnson) Trilock (DePuy) T-TAP (Biomet) Wagner* Weber (Sulzermedica) Whitesides (Dow Corning Wright) Wrightington (Howmedica) Zweymuller*

Executive summary

Objectives

- To review available evidence on the comparative effectiveness of different prostheses types in total hip replacement (THR) for adults suffering primarily from osteoarthritis.
- To develop an economic model, using cost data from two NHS orthopaedic centres, to model the cost-effectiveness of alternative prostheses under varying resource input assumptions.

Methods

The reviewers had the benefit of a large in-house database. Additional searches were conducted in Medline, 1980–95, using a modified Cochrane strategy for identifying randomised controlled trials (RCTs). Separate searches were conducted in Embase, 1990–96, to identify studies with comparison or control aspects. Further details are given in the full report.

For inclusion, studies had to provide clinical outcome data for specified prosthesis designs, comprising functional assessment, radiographic data or time to failure. There were very few RCTs. Priority was given to studies with an element of comparison. Checklists and simple rating scales were used.

NHS price data and data relevant to costs were obtained directly from two NHS Trusts and their associated orthopaedic centres. The total expected costs of THR included an element for revision of the primary operation.

Results

Appraisal of studies

Most of the studies came from specialist orthopaedic centres; this has a bearing on the generalisability of the results of individual studies. The methodological quality of the studies was generally poor, for example, lack of sample size calculations.

Comparison of prosthesis types

The following tentative conclusions can be drawn about the performance of different types of prostheses. The various designs are described in the full report.

Cemented designs in general show good survival results at 10–15 years plus. Models with good, published, comparable results (at 10 years or more) include the Stanmore, Howse, Lubinus, Exeter and Charnley. The rate of acetabular revision in cemented implants remains problematic. Newer ('second-generation') cementation techniques usually give better results than more traditional techniques.

In comparing short- to medium-term longevity between **non-cemented porous-coated** and **cemented** prostheses designs, there is no clear advantage for either type. Thigh pain is a problem associated with non-cemented porous-coated implants to which cemented designs are not prone.

The small number of studies of **cementless hydroxyapatite (HA)-coated** models report mild to moderate thigh pain in between 0% and about 5% of patients at 2–5 years' follow-up, a good result compared with porous-coated implants.

Hybrid designs are comparable with the best cemented designs for early survival (6–7 years), superior both in terms of survival and thigh pain to porous-coated implants.

The **uncoated press-fit** and **resurfacing** types of hip prosthesis have survival results that are notably inferior to those of other types. Little evidence is available on **fully modular** prostheses.

Economic modelling

Using the economic model developed in this study, the general conclusions under our assumptions are summarised below.

Prosthesis cost, hospital costs and revision rate are the components of the model with the greatest impact in terms of changing total expected costs for THR procedures.

Very high and very low estimates of hospital costs change the total expected costs for individual prostheses but have little effect on their relative cost-effectiveness compared with each other. Compared with survival data for the Charnley cemented prosthesis from 'centres of excellence', and assuming a prosthesis cost of £353 including cement, even a 'no revisions' prosthesis should not cost more than about £650 (at 1997 prices) to have equivalent total expected costs over 20 years. Only cemented prostheses are currently available at this price.

In 70-year-old men, for example, a low price prosthesis is generally more cost-effective than a high price prosthesis, even with a very low revision rate. In 40-year-old men, prostheses with high prices and low revision rates can be more costeffective than low priced prostheses with higher failure rates.

Conclusions

Policy implications

- The major concern is the proliferation of novel designs of prostheses whose effectiveness is unknown. Mechanisms for improving use of appropriate prostheses could be examined. Aspects to consider are suggested in the full report.
- Healthcare commissioners could model costs of alternative prostheses, using their local input resource assumptions and outcome data, along the lines of the model described.
- Commissioners and providers could also:
 - ascertain the range and extent of use of routinely used prostheses known to have results poorer than the best cemented designs, distinguishing different design types and taking account of age-groups, and seek audit of outcomes, including revision rates
 - in the case of significantly new designs, satisfy themselves that appropriate monitoring and evaluation is carried out.

Research recommendations

Some of the key recommendations from the main report are as follows.

General

- Improvements are needed in the design and reporting of research studies in this area.
- Further inclusion of patient-derived quality-oflife measures in studies of hip prosthesis performance is essential, as clinical hip-scoring systems do not take the patient's views into account when assessing outcomes.
- Patients' values and choices regarding quality of life in relation to THR should be investigated.

Prosthesis types

- Reporting of longer follow-up studies, especially of hybrid and cementless HA-coated models, is required in order to assess further their early promising outcomes. Follow-up of the coated acetabular component of hybrid implants is required to ascertain the medium- and long-term performance of this prosthesis design.
- Results for thigh pain and longevity in HA-coated models require longer follow-up periods. The extent and significance to patients of thigh pain associated with porous and HA-coated implants should be assessed. Longer follow-up assessments are also required for porous-coated cementless and fully modular designs.
- Further exploration is required of the associations between radiographic signs of loosening/migration and later mechanical failure.
- More up-to-date information is needed on the use of new cementation techniques, so that their use can be encouraged.

Chapter I Introduction

Total hip replacement (THR) has, since the 1960s, become one of the most frequent orthopaedic procedures undertaken in the NHS; it is, in general, extremely effective in pain relief and improved physical function in, typically, patients aged 60 years or more who are suffering from osteoarthritis. It is an expensive procedure and substantial resources are devoted to it. In the UK, in the year 1994/95, some 32,500 primary replacements were performed within the NHS (according to Hospital Episode Statistics). THR performs very favourably in cost–utility studies that compare it with other surgical procedures.

In assessing prosthetic technology, it is easy to believe that if an optimal design for the implant could be created in bioengineering laboratories, then a standard optimal effectiveness could be defined and implemented across health services. However, THR is a clinical service and such a technical solution, even if it could be engineered, would not have this effect because of the wide range of other factors which necessarily contribute to overall outcomes of this intervention. These factors include:

- surgical technique
- · surgical approach
- surgeons' experience
- operating theatre environment
- effects of prophylaxis for thrombosis and pulmonary embolism
- rehabilitation procedures
- patient factors such as bone quality and severity of disease.

Interpreting the evidence on the performance of different prosthesis designs is thus difficult.

Hip prostheses technology is continually changing and many new designs and methods of fixation have been experimented with since the original Charnley Low Friction Arthroplasty cemented concept of the 1960s. Some prosthetic designs have identifiably better outcomes than others, and some fail early and spectacularly. THR technology has been, to some extent, a victim of its own success as its use has been extended to include younger age groups and as increases in the longevity of implants are sought. Repeat THRs (revisions) perform notably less well than primary replacements and, clinically, revisions are regarded as something to be avoided if possible.

The rationale of supply and demand underlying the proliferation of alternative designs, fixation methods and surgical instrumentation is difficult to interpret. There is no statutory or nationally coordinated professional monitoring of processes of innovation and diffusion in the UK. Factors contributing to the difficulty of interpretation include:

- the commercial interest of manufacturing companies active in supplying the orthopaedic profession
- orthopaedic surgeons' creativity and ingenuity
- difficulties in interpreting the comparative results – especially short-term results – of different hip technologies.

In a somewhat critical discussion, orthopaedic innovation in THR technology internationally has been referred to as a 'trial-and-error culture'.¹ Interviews conducted by our research team have indicated that manufacturers exert, in various ways, a degree of influence over the prosthesis models which surgeons might prefer and the choice available to them. Some orthopaedic surgery departments, for example, are supplied by a single manufacturer.

It is known that over sixty different models of THR prostheses are used to at least some extent in the UK. Recent trends in new prosthesis technology have been towards new methods of cemented fixation and various designs of uncemented component. In most cases, uncemented components are significantly more expensive per unit than cemented components (in part, at least, reflecting more complex production processes), the price range in the UK being of the order of £300-400 to £1500-1600 in 1996/97. Such differences have major implications for the comparative cost-effectiveness of alternate technologies and, hence, for the total hospital and other costs associated with THR procedures.

The major interrelated issues in the use of THR technology in the NHS are:

- the proliferation of new models in the market for prostheses
- the comparative performance following implantation of different types with different costs (performance includes primarily the longevity of implants and their effectiveness in pain relief and functional improvement).

More detailed current issues are:

- · cemented versus cementless designs
- indications for different patient groups such as age groups
- optimal alloys for components in terms of elasticity,²⁻⁴ biocompatibility⁵ and abrasive wear³
- bearing surface materials at the interface of the head and cup components
- pain implicated with uncemented stem components
- the relative merits of different types of coating on uncemented components.

Some authors have suggested that design goals for the hip prosthesis are actually incompatible^{1,6} and that this is seldom acknowledged.¹ There are a number of examples:

• strengthening of the cement–prosthesis interface may weaken the cement–bone interface and vice versa

- modular components must try to allow for optimal fit and for maximum initial stability at the same time
- stems must try to be flexible in order to avoid 'stress shielding' (leading to atrophy of the surrounding bone) but be stiff enough for initial stability to promote ingrowth of bone and avoid damage at the boneprosthesis interface.

Aim of this review

The major focus of this review is on different types of prosthesis technology in terms of methods of fixation. Somewhat less attention is given to related issues such as cementation technique and the mechanics of component loosening associated with different metal alloys or other materials.

This report forms part of an extended systematic review of the effectiveness and cost-effectiveness of total hip prostheses. It includes a critical overview of published research literature on the performance of prosthetic technology in THR and an economic appraisal of the implications of different costs of prostheses in the light of evidence about survival of different models. This takes the form of an economic model which can be used – by healthcare purchasers or providers – to estimate the effects on total THR costs of varying the cost of resource inputs to the model, including the price of prostheses.

Chapter 2

Indications for primary total hip replacement

T HR is undertaken for severe degenerative joint disease, especially arthritis. The two main conditions treated by this approach are osteoarthritis and rheumatoid arthritis. Osteoarthritis is associated with advancing age while rheumatoid arthritis is more likely to occur in young adults. Other diseases treated by the procedure include avascular necrosis, congenital dislocation, Paget's disease, ankylosing spondylitis and traumatic arthritis.

There is uncertainty regarding both the definition of exact criteria for hip replacement surgery and the symptoms which might be associated with maximal benefit from surgery. Variation in the rates of THR surgery across regions in England⁷ raise questions about the consistency of decision-making in general practitioner (GP) referrals and in choosing THR treatment. Orthopaedic surgeons have been "making-do without randomised trials"⁸ of case selection for hip joint replacement.

Few studies have examined the question of optimal indications for THR in detail. Trials and other studies tend to take surgery as indicated and randomise patients by type of prosthesis or surgical method. Some consensus statements, aimed at distilling opinions on good practice in this area, have been made but the shortcomings of such approaches should be recognised. The US National Institutes of Health Consensus Development states that "candidates for THR should have radiographic evidence of joint damage and moderate to severe persistent pain or disability or both that is not substantially relieved by an extended course of nonsurgical management".9 A recent study employing the Delphi technique specified criteria for identifying appropriate patients for referral to a surgeon for consideration for arthroplasty.¹⁰ Pain and functional status were the key criteria but age, ability to work and other important factors were also considered. Orthopaedic surgeons in the UK who were interviewed as part of this study also

supported the primacy of pain and function, with pain being seen as the most important factor. An initiative in New Zealand, which aims at ensuring that those most in need are offered surgery, has involved the development of a scoring system, again using consensus methods, for determining priority for major joint replacement. Pain is the most important component of this score, with functional activity, movement ability, deformity, multiple joint involvement and ability to live independently all contributing to a lesser extent.¹¹

It may be concluded that the principal indications for THR are pain and functional limitation; however, this conclusion is the result of consensus rather than primary research. Disease-specific pain is, of course, difficult to define both clinically and as an outcome measure in hip prosthesis follow-up studies.

While there is a basic consensus on the primary indications for total hip replacement per se, more detailed indications for the procedure are less clear. During the 1970s and 1980s, patients aged between 60 and 75 years were considered to be most suitable for the procedure; however, more recently, this age range has been extending in both directions. In younger age groups, procedures such as osteotomy and fusion may be considered as alternatives but there is no evidence to suggest that these are preferable. Data on potential risk factors such as age, weight and medication are insufficient guides to treatment for individual patients and there are no clear indications for different surgical approaches and techniques. Choices of different types of implant for different patient groups are surrounded by uncertainty and variations in surgical practice. The extent to which surgeons exercise choice of type of prosthetic component in relation to patient criteria such as age (as a proxy for activity level), diagnosis, bone stock quality and weight (body mass index) is unknown.

Chapter 3

Evolution of different types of prosthetic technology for total hip replacement

The periods of major development in THR technology from the initial cemented procedure to the more recent major design innovations are shown in *Table 1.*

The theoretical advantages and disadvantages of the different designs and fixation methods of hip prostheses are not discussed in detail here. Basic differences between the different types are described below.

In the 1970s, high failure rates of the early **cemented** THRs were found, which were characterised by bone loss (osteolysis) and mechanical loosening of prostheses. The cause was considered by many to be 'cement disease', that is, a direct reaction between the 'cement' (i.e. polymethyl methacrylate) and the body tissue. This belief was a major stimulus in the search for alternative solutions to the problem of long-term fixation and led to the concept of cement-free fixation. Methods of cementation have themselves evolved and are conventionally classified into the three 'generations' with the characteristics noted in *Table 1*.

Various **cement-free** methods have been developed which can be summarised broadly as:

- **press-fit** methods, in which fixation is sought by closeness of fit between prosthesis and bone, often assisted mechanically by techniques such as threading and augmentation by screws, nails or pegs, and 'macro-interlock' design features such as ribbed stems designed to improve fixation by wedging
- **porous-coated**, in which cementless technology is treated at surfaces adjacent to bone with an inert microporous coating in the form of mesh or beads with the aim of encouraging ingrowth of bone into the prosthesis surface
- hydroxyapatite- (HA-) coated, which is similar to porous coating in concept but the surfaces adjacent to bone are coated with HA, a form of calcium phosphate ceramic considered to be biologically active and capable of direct chemical bonding to bone.

TABLE 1 Major developments in THR technology

| Prosthesis type | l 960s | l 970s | 1980 s | 1990s |
|-----------------------------|--------|--------|---------------|-------|
| Cemented | | | | |
| 1st generation | | | | |
| Finger packing | 1960s | | | |
| 2nd generation | | | | |
| Intramedullary femoral | | mid- | | |
| plug, cement gun, | | 1970s | | |
| superalloys for stems | | | | |
| 3rd generation | | | | |
| (some still regarded | | | mid- | |
| as experimental) | | | to late | |
| Pressurisation, porosity | | | 1980s | |
| reduction, precoating, | | | | |
| rough surface, centrisation | | | | |
| Ceramic (heads/cups) | | late | | |
| | | 1970s | | |
| Uncoated press-fit | | late | | |
| cementless | | 1970s | | |
| Porous-coated | | | early | |
| cementless | | | 1980s | |
| Hybrid (cemented stem | n/ | | early | |
| uncemented cup) | | | 1980s | |
| HA-coated cementless | | | late | |
| | | | 1980s | |
| Fully modular | | | late | early |
| | | | 1980s/ | 1990s |

In **hybrid** models, a cemented stem is combined with an uncemented cup, which retains the relatively good performance of cemented stems but substitutes possibly superior cement-free cups; this allows immediate weight-bearing and, hence, may be seen clinically as suitable for older patients unable to use crutches.

In the **fully modular** type of prosthesis, the problem of achieving close anatomical fit is tackled by making available a range of sizes of separate subcomponents of the total prosthesis, including the acetabular cup, the femoral stem, and the separate sleeve and head of the femoral component. Manufacturers are developing increasing modularity, and an increase in modular connections in a prosthesis leads to increased production costs. **Ceramic** heads and cups (among other combinations of materials) have been developed in an attempt to lessen wear and thus reduce the production of damaging particles at the bearing surfaces of the prosthesis.

Chapter 4 Types of outcome measure

There are, broadly, three types of outcome measure available for review in the orthopaedic literature on total hip prostheses:

- the lifespan of the prosthesis, which is usually referred to as its 'survival' and is typically represented by survivorship analysis or revision rates (i.e. rates of replacement of prostheses)
- prosthesis function *in situ*, which is measured typically by one of several standardised clinical hip scoring systems (outlined below) and which includes symptomatic loosening
- radiographic definitions of possible failure, including bone loss (osteolysis), subsidence of the stem component, migration of the cup component and wear of materials.

In practice, revision rate/survivorship is reported differently in different studies. Many studies use 'survival analysis' to assess the longevity of implants. This calculates, in a given cohort, the number of implants surviving unrevised each year as a proportion of those still *in situ*. In terms of the performance of the prosthesis itself, the key criterion for failure is revision for **aseptic loosening**, that is, as far as possible the defined outcome is caused by characteristics of the prosthesis rather than by confounding factors such as infection or dislocation (which may be due to accidental falls). In practice, reporting of the causes of revision is variable and sometimes just the revision rate is given without any qualification regarding its interpretation. In such cases, it is impossible to know whether causes of revision normally irrelevant to the prosthesis technology, such as infection, have been included. Other dimensions used in prosthesis survival analysis, which may or may not be included in different authors' definitions of failure, include radiological evidence of loosening and patient tolerance of symptoms. Some studies include 'pending revisions', others do not.

The total mechanical failure rate is also frequently reported. This refers (usually) to revision rates caused by aseptic loosening combined with radiographic evidence of loosening, fracture or other mechanical failure of components.

The main clinical hip scoring systems are briefly described in *Table 2.* Scores are allocated by a clinician. The Harris and the Merle d'Aubigne systems are the ones most frequently reported in the studies reviewed here.

Pain is conventionally graded from 'mild' through 'modest' to 'severe'. Some studies report the proportion of patients found to be 'pain-free'. A problem with these grades is that studies rarely indicate whether pain is related to context; for example, whether it is related to a particular

| TABLE 2 | Most frequent | y cited clinical | I hip scoring systems |
|---------|---------------|------------------|-----------------------|
|---------|---------------|------------------|-----------------------|

| Merle d'Aubigne (also in a version revised by Charnley) | 3 dimensions: pain, mobility, walk: each scored 0–6 | Hip function graded as 'good; fair; medium; poor' |
|--|--|---|
| Harris | 4 dimensions (score): pain (0–40), function (0–47), range of motion (0–5), absence of deformity (0–8) | Combined score = 100; < 70 poor; 70–79 fair; 80–90 good; 90–100 excellent (In studies, 'good' and 'excellent' results frequently classified together, and a 'mean Harris' combined score given for a cohort.) |
| Johnston | 5 dimensions: pain, activity, limp/walk, walking aid, ambulation time | |
| HSS (Hospital for Special Surgery) | 4 dimensions: pain, walk, range of motion, function: each scored 10 points | Combined: 32+ excellent; 24–31 good; 16–23 fair; < 16 poor |

level of physical activity. Grading is undertaken by the clinician.

Thigh pain, which is fairly frequently reported in studies of uncemented implants because it appears to be a problem in at least some of these, has rarely been reported for cemented implants and cannot be inferred from the pain dimensions included in the common hip scales. This makes comparison of this aspect between the two broad technologies difficult. Some studies in which this outcome is compared for different types of prosthesis are reviewed later in the chapters in which the key results of clinical studies are presented.

Of the outcome measures commonly used in the studies reviewed, reporting of radiographic measurements is the most diverse and difficult to interpret. It is frequently stated that radiographic results do not correlate with clinical findings and prosthetic survival; however, this is a controversial subject in which the evidence from one study to another is conflicting. The possibility of predicting later failure from early radiographic measures is an important issue, especially in the context of the proliferation of unproven novel designs and technologies. In one study it was suggested that failure of the femoral component due to loosening can be predicted with 86% specificity and 78% sensitivity using standard X-ray techniques.¹² Migration/ subsidence (of the stem component) of greater than 1.2 mm per year¹² or at 2 years post-implant¹³ have been suggested as the best threshold for prediction of failure.

Radiographic evidence is treated as a standard outcome measure in many studies of hip prosthesis technology, regardless of its potentially predictive role. The most common dimensions analysed are loosening, migration (especially of the acetabular component) and subsidence (of the stem). Again, there is variation in the thresholds and criteria used by different authors in defining these measures. Other measures used are stability, presence of continuous radiolucent lines (indicative of possible loosening) around components, change in orientation of components, signs of wear or abrasion of prosthetic surfaces and presence of particulate debris associated with wear.

A number of negative outcome measures are not included in the summaries of studies critically appraised in this review because they do not aid comparison of performance of the prosthetic technology *per se.* These include:

- infection (for example, Ahnfelt and colleagues,¹⁴ in their analysis of 15 different implant models, report no difference between implants when failure leading to revision for infection is the end-point)
- dislocation
- postoperative fracture (often associated with accidental falls)
- mortality
- intra-operative complications (e.g. blood loss)
- deep vein thrombosis and pulmonary embolism.

Measurement of quality of life, pain, activities of daily living and satisfaction, using patient-derived measures, are notably absent from the literature reviewed. Issues in the measurement of outcomes of THR have been discussed in more detail elsewhere (for example, by Heaton *et al.*¹⁵) and form the focus of a separate report commissioned by the NHS R&D Health Technology Assessment programme.

Chapter 5

Review methodology: search strategies, selection criteria and critical appraisal methods

Literature search

The reviewers had the benefit of a large bibliographic database compiled within their department to support a number of research projects on epidemiology and service provision for THR. Additional searches were conducted employing a modified Cochrane strategy for identifying randomised controlled trials (RCTs) on Medline, 1980-95, and broad criteria for THR/arthroplasty for 1995 on Medline and Embase. As the review project progressed, ad hoc searching identified a number of important studies published in 1996. Separate searches using a variety of terms (such as control*, versus, compar*, match*) were conducted on Embase, 1990-96, to identify studies with comparison or control aspects in the study design. The searching was limited historically because prosthesis models change continually; hence, collecting evidence on superseded models was considered to be unproductive. A number of individuals and organisations, for example, the Medical Devices Agency, were contacted directly.

Selection criteria

The following criteria were applied:

- identifiable type of total hip prosthesis, including named models not currently used in the UK
- clinical data given (excluding, for example, laboratory-only studies)
- patient group: adult with a primary diagnosis of hip arthropathies/congenital deterioration, excluding hip fracture
- follow-up period specified
- outcome definition for prosthesis failure to include survivorship and/or revision rate and/or radiographic criteria
- type of evidence: observational or experimental design
- stage of study (end/interim) reported
- only English language articles or abstracts included.

In addition, a large number of bioengineering and prosthesis retrieval studies of the mechanics of loosening, migration, subsidence, and laboratory studies of wear of material components have been collected; however, these are not reviewed in this report.

Excluded studies

Many studies were excluded from the review following inspection of the full text of retrieved articles. The reasons for exclusion at this stage included:

- unusual diagnostic profile of patient group
- lack of primary data included in the article
- rare and obsolete prosthesis design
- high proportions of revision operations in the study group.

The exclusions included a small group of studies of uncemented porous-coated designs with very short (2–3 years) follow-up periods.

Critical appraisal methods

A total of 233 studies giving primary data were included in the review.

It is difficult to isolate the outcomes associated with the prosthetic technology and design in THR from potentially confounding variables, especially surgical techniques, surgeon-specific factors and patient characteristics. Priority in the appraisal of studies has thus been given to studies with an element of comparison or control of these variables. There are very few RCTs to draw upon.

Checklists were used to control the appraisal process. Separate checklists were used for RCTs, non-controlled comparative studies and observational/cohort studies without comparative features. Each study was reviewed by one of the research team (either AF or GK). Blinding to author or affiliation was not employed. The checklist criteria are presented in chapter 6. These were adapted from the similar approach used by Cowley in her Medline-based review of the same subject for the Australian Institute of Health and Welfare.¹⁶ Studies were given a rating A, A/B, B, B/C or C based on the extent to which the appraisal criteria were met. In the presentation of results, ratings A, B and C only have been used for the sake of simplicity; A/B ratings were deemed to be A-rated and B/C ratings were deemed to be B-rated. Definite failure to meet one of the key criteria resulted in a C rating. Studies which met all key criteria were rated A or B, depending upon performance against the other criteria. Criteria were not given explicit weights and were not regarded as of equivalent weight in these decisions. They thus have a subjective component. The ratings provide a simple method of summarising the quality of the studies reviewed using the checklist criteria and, hence, should be regarded as shorthand summaries of the detailed appraisals carried out for each study.

The main classifications used in structuring the presentation of studies in this report are the type of research design and types of prosthesis. The criterion-by-criterion appraisal of each study is presented in the appraisal tables in the appendix to this report. Key data were extracted for each study and these are presented in the data tables in the appendix. Individual written summaries of each RCT reviewed are presented at the beginning of the appendix.

Publication bias

The major focus of this review is on the comparative effectiveness of different prostheses rather than the effect size associated with prostheses compared to another type of intervention. Formal methods of assessment of publication bias cannot be applied to the small number of RCTs available for this review. It is possible that more reports of studies giving poor results associated with particular models may be published in non-English language journals, which were not included in this review, but the proportion of the reviewed studies reporting failures and 'poor' results is relatively high, suggesting fairly open editorial policies in which publication bias toward positive or 'good' results is not a major concern. A very small number of English-language abstracts of non-English articles have been included where sufficient information was available. These are noted in the appraisal tables in the appendix. Further abstracts were scrutinised but it was judged that, for the limited additional information likely to be obtained, translation was not warranted. No RCTs were covered by these abstracts. A more important factor affecting interpretation of results is the institutional origin of studies, the majority coming from specialist and teaching centres. Also noteworthy is the small proportion of studies in which some of the authors may be seen to have a direct vested interest in the commercial prospects of the particular component reported upon.

Chapter 6

Summaries of effectiveness studies and results of critical appraisal

he majority of studies of the outcomes I of hip prostheses in primary THR are observational in design. Few RCTs have been published. This review has tried to maximise the use of studies with an element of comparison between prosthesis types. The most studied single model is the cemented Charnley. The great majority of studies have appeared in a small number of specialist orthopaedic journals and emanate from specialist orthopaedic centres and departments, mainly in teaching hospitals. About 12% of the reviewed studies originate in the UK. Length of follow-up is inadequate for the full evaluation of the longevity of more recently introduced types of prosthesis. The methodological quality of studies is, in general, low, especially notable being the lack of sample size calculation in any of the reviewed studies. In most studies, the sample sizes actually reported appear to be notably smaller than would be ideally recommended to achieve valid generalisable results.

Summary of study characteristics

Numbers of reviewed studies for different comparisons and prosthesis types Meta-analyses

A single meta-analysis exists in the orthopaedic literature on total hip prostheses¹⁷ and is commented on later in this chapter.

RCTs and comparative studies

A total of 78 RCTs and comparative studies are included in this review (17 RCTs, 61 other comparative studies).

The prosthesis (or prosthesis type) comparisons which these studies make possible overall are summarised in *Table 3.*

It can be seen that the most numerous comparisons in the literature are between alternative cemented designs, followed by

| Type of prosthesis | Cemented - Charnley | | Ceramic | HA- coated | Hybrid | Modular | Press- fit | Porous | Re- surfacing |
|---------------------|------------------------|----|---------|---------------|--------|---------|---------------|--------|------------------|
| Cemented – Charnley | I | | | | | | | | |
| Other cemented | 12 | 15 | | | | | | | |
| Ceramic | I | 3 | I | | | | | | |
| HA-coated | I | 2 | | | | | | | |
| Hybrid | 2 | 2 | | | | | | | |
| Modular | | I | | | | I | | | |
| Press-fit | 2 | 5 | | 5 | | | 4 | | |
| Porous | 3 | 10 | I | 4 | 6 | | 2 | 2 | |
| Resurfacing | 2 | 5 | I | | | | | 2 | |

TABLE 3 Numbers of trials and comparative studies included

NB: This table excludes six studies which did not fit into the above divisions, one being the meta-analysis referred to above. A blank cell indicates that no study for this comparison was found in the review.

cementless porous-coated versus cemented, HA-coated and hybrid designs of prothesis.

Other RCT/comparative studies

There are 11 other studies which are not straightforward prosthesis versus prosthesis comparisons. These are dealt with separately from the above studies in chapter 10. They include comparisons of patient variables and fixation types and techniques, together with reports assessing why outcomes such as dislocation and fracture may occur.

Observational studies

A total of 145 observational studies were reviewed (see *Table 4*).

| Type of prosthesis | Number of studies |
|--------------------------|-------------------|
| Cemented – Charnley | 45 |
| Other cemented | 29 |
| Uncemented – press-fit | 13 |
| Uncemented porous-coated | 34 |
| Uncemented HA-coated | 9 |
| Hybrid | 6 |
| Others | 5 |
| Total | 145 |

TABLE 4 Numbers of observational studies reviewed

A further six observational studies of uncemented threaded press-fit acetabular components were reviewed for data extraction purposes but not appraised, because this design has generally been abandoned.

Journals of publication

The journals in which the reviewed studies of hip prostheses mainly appear and the number of articles are presented in *Table 5* (RCTs and comparative studies) and *Table 6* (observational studies).

In *Table 5,* two studies which were published in separate journals *(Clinical Orthopaedics and Related Research* and *Canadian Journal of Surgery)* reported on the same cohort of patients and are jointly appraised in this report, although they are recorded separately here. The single metaanalysis study was not included.

Only four of the RCTs and comparative studies listed in *Table 5* appeared in non-orthopaedic

TABLE 5 Journals in which RCTs and comparativestudies appear

| Journal name | Number of studies | Percentage of total |
|---|----------------------|------------------------|
| Clinical Orthopaedics and Related Research | 20 | 25 |
| Journal of Bone and Joint Surgery [American] | 10 | 13 |
| Journal of Bone and Joint Surgery [British] | 12 | 15 |
| Combined | 22 | 28 |
| Acta Orthopaedica Scandinavica | П | 14 |
| Journal of Arthroplasty | 8 | 10 |
| Archives of Orthopaedic and Trauma Surgery | 6 | 8 |
| Others | 12 | 15 |

TABLE 6 Journals in which observational studies appear

| Journal name | Number of studies | Percentage of total |
|--|----------------------|------------------------|
| Clinical Orthopedics and Related Research | 41 | 28 |
| Journal of Bone and Joint Surgery (American + British combined) | 46 | 32 |
| Journal of Arthroplasty | 10 | 7 |
| Acta Orthopaedica Scandinavica + Acta Orthopaedica Belgica | 9 | 6 |
| Others (e.g. Orthopedics, Journal of Orthopaedics and Rheumatism, Orthopedic Clinics of North Americ | 39 ca) | 27 |

journals; one each in: *Canadian Journal of Surgery, Australian and New Zealand Journal of Surgery, Investigative Radiology* and *Keio Journal of Medicine.*

Only two of the observational studies *(Table 6)* appeared in non-orthopaedic journals or other specialist sources: *Canadian Journal of Surgery,* and *Australian and New Zealand Journal of Surgery.*

Overall, it is clear that a small number of specialist orthopaedic journals account for the vast majority of publications of primary research studies on total hip prostheses. Very few studies are published in generalist medical journals.

Country/area in which studies are conducted RCTs and comparative studies

The countries of origin of the RCTs and comparative studies are shown in *Table 7*, both in terms of the number of studies and as percentages of the total. The one joint study, between the UK and Switzerland, is recorded for both countries. The single meta-analysis study is not included.

| TABLE 7 | Country of origin | of RCTs and | comparative studies |
|---------|-------------------|-------------|---------------------|
|---------|-------------------|-------------|---------------------|

| Journal name | Number of studies | Percentage of total | |
|---|----------------------|------------------------|--|
| USA | 34 | 43 | |
| Sweden | 12 | 15 | |
| UK | 9 | П | |
| Norway | 4 | 5 | |
| Switzerland | 4 | 5 | |
| Austria | 3 | 4 | |
| Denmark | 3 | 4 | |
| Finland | 2 | 3 | |
| Canada | 2 | 3 | |
| Others | 6 | 7 | |
| NB: List includes one joint study between the UK and Switzer- | | | |

NB: List includes one joint study between the UK and Switzerland, which is recorded for both countries. The single metaanalysis study is not included.

Notably, 47% of RCTs came from Sweden and 18% from the UK; 41% of the comparative studies came from the USA and 10% from the UK.

Observational studies

The approximate percentages of reviewed observational studies by country/area are presented in *Table 8.*

Types of hospital from which published research originates

The great majority of studies came from specialist orthopaedic centres or teaching hospitals. A small number of district general hospitals can be identified, and a few studies report multicentre results in which all types of hospital have been included. The preponderance of specialist centres must be borne in mind when interpreting the studies' results.

Diagnostic profiles of patient groups

The major primary diagnosis in the great majority of published studies is osteoarthritis of the hip. In most

| Country of origin | Percentage of total |
|-------------------|---------------------|
| UK | 13 |
| Other European | 30 |
| USA | 41 |
| Others | 16 |

series the proportion of patients with osteoarthritis varies between 50% and 80%. The next most prevalent condition is rheumatoid arthritis. In studies of patients in younger age groups the proportion with rheumatoid arthritis tends to be higher. Very few of the cohorts studied have been confined to patients with a single disease entity. Few studies perform subgroup analysis by diagnostic group.

Maximum follow-up periods

The period of follow-up is obviously important in the evaluation of prosthesis technology. Where possible, the maximum stated follow-up period reported in each of the studies reviewed are summarised in *Table 9* (RCTs and comparative studies) and *Table 10* (observational studies). In those studies in which mean or median follow-up period only was stated, an informed guess of the likely maximum period has been made, based on other studies and publication dates. Comparison of these results gives an indication of the typical length of follow-up available from published studies for the different types of prostheses. Losses to follow-up and death mean that numbers of hips reviewed at the maximum period are frequently low.

TABLE 9 RCTs and comparative studies: maximum follow-up periods

| Type of prosthesis | Number of studies | Approximate average maximum follow-up period (years) |
|-------------------------|-------------------------|---|
| Cemented – Charnley | 12 | 13.5 |
| Other cemented | 52 | 9 |
| Ceramic | 4 | 9 |
| Uncemented press-fit | 16 | 4.5 |
| Uncemented porous-coate | d 23 | 5 |
| Uncemented HA-coated | П | 3 |
| Hybrid | 6 | 5 |
| Modular | I | 6 |
| Resurfacing | 4 | 6.5 |

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TABLE 8 Country of origin of observational studies

| TABLE 10 | Observational | studies: maximum | follow-up periods |
|----------|---------------|------------------|-------------------|
|----------|---------------|------------------|-------------------|

| Type of prosthesis | Number of studies | Approximate average maximum follow-up period (years) |
|-------------------------|-------------------------|---|
| Cemented – Charnley | 45 | 15.5 |
| Other cemented | 29 | 10 |
| Uncemented press-fit | 13 | 7–8 |
| Uncemented porous-coate | d 33 | 7 |
| Uncemented HA-coated | 10 | 4 |
| Hybrid | 6 | 6 |

It can be seen clearly from the tables that followup periods for non-cemented types are on average only short term. The longest follow-up period of studies of non-cemented prostheses included in this review was about 10 years.

Sample size

None of the reviewed studies of any type reported a prospective calculation to estimate required sample size.

Sample size as a criterion was not included in the checklist of criteria because the range of different outcome measures used in studies have different implications for sample size. A large difference in clinical hip scores, for example, may be detected with a relatively small sample but small differences in relative survival of prostheses, when revision of the hip is the definition of survival, requires relatively large sample sizes.

An analysis of the reviewed studies, according to our own sample size calculations under the assumptions for each type of study design, is presented below.

RCTs and comparative studies

Two sample size calculations have been made, one stringent and the other more relaxed. In the first, in order to detect a difference of 4% in the survival rates between two prosthesis designs, assuming an expected survival rate of 90% at 20 years (95% confidence interval, 80% power) would require an achieved sample size of 1085 hips per arm. Allowing for death during follow-up, and assuming mean age at operation of 65 years, an initial sample size of 3600 hips per arm might be required at this level of stringency (fewer for younger age groups). Alternatively, assuming a survival rate of 80%, in order to detect a relatively large difference of 10% in prosthesis survival would require an achieved sample size of some 313 hips per arm, or about

480–500 hips per arm if a total follow-up of 300 hips per arm was required for 10 years.

The numbers of reviewed RCTs and comparative studies of prosthesis versus prosthesis meeting these sample size criteria are as follows:

- > 3600 per arm none
- >1000 per arm one (Havelin, *et al.*, 1994¹⁸)
- > 480 per arm none except the above¹⁸
- > 300 per arm the above¹⁸ plus two (Ebramzadeh, *et al.*, 1994;¹⁹ Schreiber, *et al.*, 1993²⁰).

In summary, only three of the RCTs and comparative studies reviewed have sample sizes enabling statistically valid comparisons for hip survival between prosthesis groups over the defined minimum of 300 hips.

Observational/cohort studies

A sample size of 600 hips is required in order to have a 95% confidence interval with an estimated precision of ± 0.04 (i.e. confidence interval with width of 8%), for an assumed 60% prosthesis survival rate at 20 years. Larger samples would be required in order to have the same precision for higher percentage survival assumptions. In comparison to studies of the survival of cemented prostheses with long follow-up, a 60% survival rate is a conservative assumption. This sample size estimate assumes that total follow-up is possible which, in practice, it is not because of the death of a proportion of the initial recipients of a prosthesis (this is likely to be about 70% if the mean age at operation is 65 years).²¹ Thus, to achieve total follow-up of about 600 patients would require an initial cohort of some 2000 patients (this figure does not take account of the fact that most studies include a proportion of surviving patients who are lost to follow-up).

Only three of the 145 observational studies reviewed include cohorts fulfilling this sample size criterion, those by Ahnfelt and colleagues,¹⁴ based on the multicentre Swedish registry, Dall and colleagues,²² both in cohorts given the Charnley prosthesis, and Mohler and colleagues,²³ followingup the Iowa Hip cemented prosthesis.

The great majority of observational studies have cohort sizes of between 100 and 500 hips.

Appraisal results

Full results of the appraisal of individual studies are given in the appraisal tables in the appendix. The numbers of A-rated studies and the percentages of

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studies meeting the individual appraisal criteria are summarised below. The rating procedure used is that described in chapter 5.

Study using meta-analysis

The single meta-analysis study¹⁷ combines the data from observational studies internationally of uncemented press-fit threaded acetabular cups and compares the results to cemented and porouscoated control groups, also using combined data. Extracted data from the study are included in the data tables in the appendix but the study has not been included in the checklist appraisal. The practice of combining data from observational studies is, in principle, methodologically weak because of the effects of confounding and selection and other biases in single, observational, nonrandomised studies. Even given the very careful selection of studies which the authors achieved, it is difficult to account fully for possible sources of heterogeneity in combined studies.²⁴ However, it should be noted that the results of the major comparison of relative effectiveness in this metaanalysis are supported by orthopaedic surgical practice internationally, in which use of the threaded cup design has been largely abandoned.

A-rated RCTs and comparative studies

The numbers of A-rated RCTs and comparative studies are presented in *Tables 11* and *12*.

The number of A-rated observational studies are presented in *Table 13.*

Proportions of studies meeting appraisal criteria The overall appraisal results for each criterion

 TABLE 11
 RCTs and comparative studies: number of A-rated studies for prosthesis versus prosthesis comparisons

| Type of study | Number of studies A | Number of -rated studies |
|---------------|------------------------|-----------------------------|
| RCT | 15 | ²⁵ |
| Comparative | 51 | 0 |

TABLE 12 Other RCTs and comparative studies: number of A-rated studies

| Type of study | | f Number of A-rated studies |
|---------------------------------------|----|--------------------------------|
| RCT | 2 | 0 |
| Comparative | 10 | 2 ^{26,27} |
| NB: Excludes the meta-analysis study. | | |

TABLE 13 Observational studies: numbers of A-rated studies for each prosthesis type

| Type of prostheses | | of Number of A-rated studies | |
|--|-------|---------------------------------|--|
| Cemented – Charnley | 45 | 7 | |
| Other cemented | 29 | 12 | |
| Uncemented press-fit | 13 | I | |
| Uncemented porous-coat | ed 33 | 9 | |
| Uncemented HA-coated | 10 | 6 | |
| Hybrid | 6 | I | |
| (See appraisal tables in appendix for details) | | | |

for each type of study design are summarised in *Tables 14–17.*

In addition to the appraisal results for RCTs presented in *Table 14,* two other RCTs which do not make prosthesis versus prosthesis comparisons have been reviewed. They meet the appraisal criteria as follows:

| criterion 1 – neither | criterion 10 – 2 |
|-----------------------|-------------------------|
| criterion 2 – 1 | criterion 11 – 2 |
| criterion 3 – neither | criterion 12 – 1 |
| criterion 4 – neither | criterion 13 – neither |
| criterion 5 – 1 | criterion 14 – 2 |
| criterion 6 – 2 | criterion 15 – neither |
| criterion 7 – 2 | criterion 16 – 1 |
| criterion 8 – 2 | criterion 17 – neither. |
| criterion 9 – 2 | |

A number of general comments on the design of studies of hip prosthesis outcomes in the orthopaedic literature can be made on the basis of the results presented in *Tables 14–17.*

Methodological weaknesses in the studies are of particular concern in the description of study group characteristics from which representativeness might be assessed. Only one in three of the RCTs identified the method of randomisation. In the comparative studies, the major weaknesses are in descriptions of the process of assignment of patients to prosthesis groups, and in establishing the comparability of patients in comparison groups (either through matching or statistical analysis). Fewer than half of the observational studies give an account of the selection of patients included in the study (in addition, there are very few descriptions of clinical indications for prosthesis choice). Review of the observational series suggests that prosthesis selection practice is based largely on the preferences of clinicians and surgical centres.

Prospective sample size calculations have not been evident in the scientific orthopaedic literature on the clinical results of hip prostheses.

Most studies have made neither clinical nor radiological evaluations independently of the operating surgeon nor has blinding to the intervention been employed where appropriate.

| TABLE 14 Appraisal summary of prosthesis versus prosthe | esis |
|---|------|
| RCTs (n = 15) | |

| Ke | y criteria | Number meeting criterion (%) | | | |
|----|---|---------------------------------------|--|--|--|
| I | Method of randomisation identified and appropriate | 5 (33) | | | |
| 2 | Patient groups balanced or effect of any difference evaluated in valid statistical analysis | (73) | | | |
| 3 | Patients blind to prosthesis type | 2 (13) | | | |
| 4 | Assessments of clinical/radiological outcom blind to prosthesis type if possible | e 2 (13) | | | |
| 5 | Appropriate statistical analysis | 10 (67) | | | |
| 6 | Number of patients deceased or lost to follow-up reported or included in statistical analysis | 13 (87) | | | |
| 7 | Follow-up period – mean and range | 15 (100) | | | |
| 8 | Prosthesis model specified | 15 (100) | | | |
| 9 | Clearly defined criteria for measuring outcomes | 14 (93) | | | |
| 10 | Age – mean and range | 14 (93) | | | |
| Ot | Other criteria | | | | |
| П | Quantification of outcomes | 13 (87) | | | |
| 12 | Follow-up data compared with preoperative data (preferably mean and range) | e 8 (53) | | | |
| 13 | Independence of investigators (declared or no vested interest) | 6 (40) | | | |
| 14 | Numbers of men and women given | (73) | | | |
| 15 | Weight – mean and range | 9 (60) | | | |
| 16 | Preoperative diagnoses with percentages/ numbers of patients given | 13 (87) | | | |
| 17 | Clinical evaluation independent of operating surgeon | 4 (27) | | | |

TABLE 15 Appraisal summary of prosthesis versus prosthesiscomparative studies (n = 51)

| Ke | y criteria | Number meeting criterion (%) | | |
|----------------|---|---------------------------------------|--|--|
| I | Method of assignment of patients to different prostheses described, and appropriate | 17 (33) | | |
| 2 | Patients matched or differences evaluated in valid statistical analysis | 14 (28) | | |
| 3 | Appropriate statistical analysis undertaken | 32 (64) | | |
| 4 | Number of patients deceased or lost to follow-up reported or included in analysis | 29 (57) | | |
| 5 | Follow-up period – mean and range | 39 (76) | | |
| 6 | Prosthesis models specified | 46 (90) | | |
| 7 | Clearly defined criteria for measuring outcomes | 46 (90) | | |
| 8 | Age – mean and range | 37 (73) | | |
| Other criteria | | | | |
| 9 | If retrospective, patients selected without knowledge of outcomes | 27 (71) | | |
| 10 | In prospective studies, follow-up assessments blind to prosthesis type, if possible | 2 (15) | | |
| 11 | Results given for specific models (and sizes) | 38 (75) | | |
| 12 | Quantification of outcome criteria | 41 (80) | | |
| 13 | Follow-up data compared to preoperative data (mean and range) | 10 (20) | | |
| 14 | Independence of investigators (declared or no vested interest) | 12 (24) | | |
| 15 | Numbers of men and women given | 41 (80) | | |
| 16 | Weight – mean and range | 14 (27) | | |
| 17 | Preoperative diagnoses with percentages/ numbers of patients given | 34 (67) | | |
| 18 | Clinical evaluation independent of operating surgeon | 4 (10) | | |
| 19 | Radiological evaluation independent and blinded to clinical results | 3 (6) | | |

TABLE 16 Appraisal summary of other comparative studies (n = 10)

| Ke | , | Number meeting criterion (%) |
|----------|--|---------------------------------------|
| I | Method of assignment of patients to different prostheses described and appropriate | 6 (67) |
| 2 | Patients matched or differences evaluated in valid statistical analysis | 7 (78) |
| 3 | Appropriate statistical analysis undertaken | 8 (80) |
| 4 | Number of patients deceased or lost to follow-up reported or included in analysis | 9 (90) |
| 5 | Follow-up period – mean and range | 7 (70) |
| 6 | Prosthesis models specified | 9 (90) |
| 7 | Clearly defined criteria for measuring outcomes | 9 (90) |
| 8 | Age – mean and range | 9 (90) |
| Ot 9 | her criteria If retrospective, patients selected without | |
| <i>.</i> | knowledge of outcomes | 5 (56) |
| 10 | In prospective studies, follow-up assessmer blind to prosthesis type, if possible | nts NA |
| П | Results given for specific models (and sizes |) 6 (60) |
| 12 | Quantification of outcome criteria | 9 (90) |
| 13 | Follow-up data compared to preoperative data (mean and range) | 3 (30) |
| 14 | Independence of investigators (declared or no vested interest) | 4 (40) |
| 15 | Numbers of men and women given | 8 (80) |
| 16 | Weight – mean and range | 4 (40) |
| 17 | Preoperative diagnoses with percentages/ numbers of patients given | 9 (90) |
| 18 | Clinical evaluation independent of operating surgeon | 0 (0) |
| 19 | Radiological evaluation independent and blinded to clinical results | 2 (22) |
| NA | , not applicable | |

TABLE 17 Appraisal summary of observational studies (n = 145)

| Ke | y criteria F | Percentage meeting criterion | Number meeting criterion/ number applicable [*] | |
|---|---|------------------------------------|--|--|
| I | Method of selection of patients identified | 43 | 58/135 | |
| 2 | Prosthesis models specified | 100 | 145/145 | |
| 3 | Results given for specific models | 94 | 127/135 | |
| 4 | Follow-up period – mean and range | 84 | 113/135 | |
| 5 | Number of patients lost to follow-up or deceased – reported or included in analysis | 78 | 97/125 | |
| 6 | Age – mean and range | 79 | 107/135 | |
| 7 | Preoperative diagnoses of reviewed patients stated with percentages/numbers | 83 | 112/135 | |
| 8 | Clearly defined criteria for measuring outcomes/ quantification of outcomes | 91 | 112/121 | |
| Ot | her criteria | | | |
| 9 | Valid statistical analysis | 50 | 63/125 | |
| 10 | Outcome data compared to preoperative data | 40 | 44/111 | |
| П | Data given for deceased patients | 25 | 23/93 | |
| 12 | Clinical evaluation independent of operating surgeon | 8 | 9/112 | |
| 13 | Radiological evaluation independ and blinded to clinical results | ent I4 | 16/112 | |
| 14 | Numbers of men/women stated | 89 | 102/115 | |
| 15 | Weight – mean and range | 23 | 27/115 | |
| 16 | Surgical technique/approach stat | ed 77 | 89/115 | |
| 17 | Grade/experience and number of surgeons stated | 47 | 54/115 | |
| 18 | Type of hospital/centre (general/ specialist/teaching) stated | 81 | 93/115 | |
| 19 | Unilateral/bilateral results separa | ate O | 0/145 | |
| 20 | Independence of investigators (vested interest) stated | 28 | 32/115 | |
| st The 'number applicable' for each criterion varies for several | | | | |

The 'number applicable' for each criterion varies for several reasons: a number of studies which clearly failed by one or more of the key criteria were not appraised for the remaining criteria; some criteria (e.g. data given for deceased patients) were not applicable in some studies; in a very small number of studies from which data have been extracted, only an abstract was available. The denominator in calculating percentages has been adjusted accordingly.

Chapter 7

Effectiveness of hip prostheses: a summary of key results from clinical studies

G iven the methodological quality of the reviewed studies, results for different types of prostheses should be treated as estimates with wide confidence intervals. The majority of studies come from specialist centres and this is likely to have a bearing on the generalisability of the results. Clinical outcomes are measured by prosthesis survival, radiographic measurement and hip scoring. Clinical hip scoring is likely to underestimate the qualitative significance for recipients of hip implants of pain and function.²⁸ Taking these points into account, the following conclusions can be drawn about the performance of different types of prosthetic hip technology on the basis of the evidence summarised in this chapter.

Cemented designs in general show good survival results at 10–15 years plus. Models with good, published, comparable results (at about 10 years or more) include the Stanmore, Howse, Lubinus, Exeter and Charnley designs. The rate of acetabular revision in cemented implants remains problematic. There is some evidence that all-polyethylene acetabular components are preferable to metalbacked designs in terms of longevity of the implant.

Evidence of short-term comparisons between non-cemented porous-coated designs and cemented designs is equivocal. One comparative radiographic study suggests that cemented acetabular components performed better than porous-coated designs but that porous-coated stems performed better than cemented models. The first 10-year survival results for porous-coated models appear to bear comparison with the cemented models for the same follow-up period, especially when the relatively lower average age of the patient groups implanted with the porouscoated models is taken into account.

The comparative evidence strongly suggests that thigh pain is a problem associated with porouscoated (and other cementless) implants, to which cemented designs are not prone. In the observational studies of porous-coated implants, reports of thigh pain prevalence ranged between about 2% and about 25% at 2–7 years follow-up, with several studies reporting prevalence values at about the higher 25% level, including in non-loose stems. In contrast, in the small number of studies of HA-coated models, mild to moderate thigh pain was found in between 0% and about 5% of patients at 2–5 years follow-up. This is a relatively good result in comparison to reports of porous-coated implants and requires further substantiation.

Radiographic studies of cemented versus HAcoated designs suggest that HA-coated models have better early fixation and less migration than cemented models. The lesser migration of HAcoated models may be associated with less early postoperative pain, according to one comparative study. With maximum follow-up periods of only 3–4 years for this form of fixation, longer-term studies of survival and clinical results are required.

Hybrid prostheses appear to do well in the short term but the available studies cannot give any indications for their mid- or long-term results. Given wide confidence intervals, for early (6–7 years) survival this type of design can be regarded as comparable with the best cemented designs. Early survival is superior to that for uncemented porouscoated implants, and early thigh pain in cemented stem components in hybrid implants is minimal or absent compared with porous-coated designs. Longer follow-up, especially of the coated acetabular component of hybrid implants, is required to ascertain the medium- and long-term performance of this design.

Little evidence is available on fully modular prostheses. Theoretically, modularity permits greater intra-operative flexibility for the surgeon and potentially better component fit but further evidence, especially in comparison to cemented implants, is required. One comparative study suggested that a fully modular stem performed less well than cemented stems. Laboratory analysis of retrieved components suggests that mixed-alloy components are more prone to corrosion than single alloy devices.²⁹

Evidence for the performance of ceramic hips is equivocal. Wear rates are less than for other materials at the articulating surface of the joint. Comparative studies have suggested either lower or equivalent revision rates for ceramic versus cemented implants at medium-term follow-up. The implications of laboratory studies of alternative bearing surface materials require further investigation.

The uncoated press-fit and resurfacing types of hip prosthesis generally have survival results notably inferior to the other types of design available.

In the following three chapters the results of the review are presented, as follows:

- results of each comparison of different types of prosthesis taken from RCTs and comparative studies (chapter 8)
- results from selected observational studies for different types of prosthesis (chapter 9)
- results from comparative studies on selected key issues, including thigh pain, bearing-surface materials, inter-surgeon and inter-hospital comparisons (chapter 10).

A brief summary of each RCT included in this review is presented in the appendix (see page 83).

Chapter 8

Results of studies comparing different types of prosthesis

E ach type of prosthesis was compared, in turn, to all other types of THR where permitted by the available studies. For some comparisons there were more than two or three relevant studies which could be summarised (see *Table 3*) and, in this situation, only those studies with the highest rating, longest follow-up and/or survivorship results are included. One comparison noted in *Table 3* (i.e. ceramic versus resurfacing) is not included, because of poor reporting of data in the paper.

Charnley versus Charnley

Comment

Only one paper compared one form of Charnley with another. Flanges on the prosthesis may reduce the incidence of loosening but this was a small study with a C-rating and so no definite conclusions can be drawn.

Hodgkinson and colleagues, 1993³⁰

The Charnley hips were implanted flanged (n = 168) or unflanged (n = 182). The patients were well matched statistically, with an approximate mean age of 58-60 years, and 70% had osteoarthritis. All the prostheses were inserted by the same surgeons. Accurate data at 9-11 year follow-up were available for 302 prostheses (152 unflanged, 150 flanged). In total, there were 15/350 (4.3%) revisions (which included 11 patients who were excluded from further analysis because the revisions occurred before the 10-year follow-up), nine of which had radiological evidence of loosening. Analysis of demarcation lines (or the extent and width of any radiolucent lines) showed the flanged prostheses in a better light than the unflanged. No demarcation was seen at the 10-year followup in 43% of flanged hips compared with 30% in the unflanged group. Similarly, 19% of flanged prostheses had demarcations grades of 2 or more (indicating radiographic loosening) compared with 25% in the unflanged group. (These differences were significant but the statistical level was not indicated.) C-rated.

Charnley versus other cemented prostheses

Comment

Three papers were selected from others in the same category on the basis of length of follow-up and survival analyses. All of the papers making this comparison were C-rated and so leave doubts about the validity of the results. In the first two papers summarised here, Charnley is the superior hip, with Lubinus and T-28 giving closely comparable results. However, the third paper suggests the opposite - there is still an 84% survival rate for the Charnley at 10 years but this is neither as high as in other reports nor as high as the Stanmore with which it is compared (however, as no patient details were given no comment can be made on any effect this may have had). Overall, the Charnley prosthesis gives consistently good mid- to long-term results. It cannot be concluded with certainty that any of the other cemented prostheses is consistently equal to the Charnley.

Ahnfelt and colleagues, 1990¹⁴

Results from this retrospective study were taken from a Swedish multicentre registry. The patients had an approximate median age of 64 years for women and 66 years for men, with a main diagnosis of osteoarthritis. In all cases, the hips had been implanted originally between 1979 and 1986 and had required revision. Survival without revision for loosening of the original THR was observed for various prostheses. The Charnley hips had a 92% survival at 10 years (n = ?). The observed survival in eight out of ten other cemented prostheses for which results were quoted ranged from 63% (Christiansen) to 89% (Stanmore) at 10 years and from 95% (Exeter) at 5 years to 93% (Lubinus) at 9 years. **C-rated.**

Ritter, 1995³¹

The Charnley prosthesis (n = 260) was compared with four other cemented hips: Müller (n = 163), T-28 (n = 642) and 319 MOSC hips, the latter with either an all-polyethylene cup or a metal-backed cup. The average follow-up time ranged from 8.9 to 12.7 years. One surgeon performed all the operations. In all, 66% of the patients had osteoarthritis and their mean ages ranged from 59 years (Charnley) to 76 years (Müller). Over 200 patients were lost to follow-up. Of the Müller and MOSC metal-backed, 20% failed within 1 year of the operation, while only 9% of the MOSC all-polyethylene failed (compared with 14% Charnley and 10% T-28) within the same period. An analysis of survival at 10 years showed the Charnley and T-28 to be superior: Charnley, 93% (20 years = 76%), and T-28, 93% (17 years = 75%), MOSC all-polyethylene, 90% (12 years = 87%), Müller, 81% (17 years = 56%), and MOSC metal-backed, 60%. **C-rated.**

Britton and colleagues, 1996³²

In this prospective study, 205 Charnley and 982 Stanmore prostheses, implanted or implant supervised by one surgeon, were compared after a median follow-up period of 8 years. No patient details were given. In all, 7% of the hips were revised, 38/81 because of loosening. When 'revision' was the end-point, Charnley hips were reported to have an 84% survival rate at 10 years compared with 93% for Stanmore hips and, when the end-point was 'onset of slight pain', a 44% survival rate at 10 years compared with 48% for Stanmore. The survivorship curves were reported to be similar for both prostheses for the first 8 years. Beyond this, Charnley hips became significantly worse irrespective of the end-point chosen, that is, need for revision or the onset of different levels of pain. C-rated.

Charnley versus ceramic

Comment

The number of ceramic hips was too small in this study to draw conclusions about them or their performance in relation to the Charnley.

Hoffman and colleagues, 1994³³

This retrospective study involved a total of 1166 hips in 974 patients. Six surgeons (grade not specified) performed the operations in either a publicly funded hospital (66%) or at a private clinic (34%). The patients involved had an average age of 66 years and 89% had a diagnosis of osteoarthritis; there were slightly more males (54%) than females and 55% of operations were to the right side of the body. This section of the report refers to only part of the overall study. The Charnley prostheses (n = 867) had 72 failures recorded, six caused by loosening; with an annual failure rate of 1.78% and a survival rate of 73% at 15 years. The ceramic prosthesis (Autophor, n = 35) had a failure rate of 15% in 3 years, giving an annual rate of 5%. C-rated.

Charnley versus HA-coated

Comment

The numbers involved in this study were too small and the length of follow-up too short for any differences between the two prostheses types to be demonstrated unless one performed extremely badly. Further studies are needed in this area as it is an important comparison which has been neglected.

Bradley & Lee, 1992³⁴

In this RCT, the Furlong (HA-coated prosthesis, n = 97) was compared with the Charnley (n = 73). The patients (with primary osteoarthritis, average age 68 years, range 45–75 years) were randomly allocated by year of birth. A total of 139 patients were reported on at 1-year follow-up and 74 at 2-year follow-up. The results at 1 year and 2 years, based on the Harris Hip Scores, were very similar in both groups (no pain: Furlong 98%, Charnley 96%, p = ?; number without a limp, walking distance and use of walking aids, ability to climb stairs and put on shoes/socks, all had "uniformly good average results"). There were no revisions or evidence of loosening. **C-rated.**

Charnley versus hybrid

Comment

Hybrid prostheses appear to do well in the short term but the available studies cannot give any indications for their mid- or long-term results. Both studies here had a C-rating. The first had very small numbers and, although a statistical difference regarding absolute rotation was noted, it is not clear if this would translate into greater problems for the Harris-Galante prosthesis in later years and so it is difficult to comment on this result.

Onsten and colleagues, 1994³⁵

Charnley stems were implanted in both bilateral hips under the same anaesthesia in 29 patients in this RCT. One hip had a Harris-Galante type 1 cup and the other a Charnley cup. At 27 month follow-up, 21 patients (diagnosis, osteoarthritis; age range, 41–76 years) were assessed. Five Charnley and three Harris-Galante prostheses did not migrate or rotate. Mean values of absolute migration between the groups in any direction did not differ (p = 0.06-0.98) but the mean values of absolute rotation did (p = 0.08-0.008) – the Harris-Galante hips rotating the most. **C-rated.**

Callaghan and colleagues, 1995³⁶

As part of a larger study, 330 Charnley hips (follow-up minimum 20 years) and 89 Charnley hips in patients less than 50 years old (follow-up, 16-22 years) were compared to 130 hybrid hips (Harris-Galante type 1 cup plus IOWA cemented stem; follow-up, 5 years) and 61 similar hybrids used as revisions (follow-up, minimum 5 years). No patient details were given. In the Charnley groups the cup revision incidence was 10.6% in the 20-year follow-up and 13% in the younger age group; loosening was 12.8% and 37%, respectively. The stem revision incidences in the two Charnley groups were 3.2% and 2.2% for the 20-year follow-up and the young age group, respectively, while loosening was reported in 4.3% and 6.1%, respectively. This is in contrast to the hybrid groups where no revisions (or rerevisions) were reported and only one migration in the revision group occurred; however, followup was only for 5 years or more. Wear rates were also assessed in this study, with the Harris-Galante cups (28 mm head) reported as having less wear than other groups, but unfortunately no details were given. C-rated.

Charnley versus press-fit

Comment

Even at 1-year follow-up, the Charnley showed better results than the press-fit design. A reduced probability of survival, higher revision rates caused by loosening, increased risk of subsidence and general lack of performance does not inspire confidence in this type of prosthesis in comparison to the Charnley.

Wykman and colleagues, 1991³⁷

Charnley and Honnart Patel-Garches prostheses were each inserted into 75 patients during an RCT; 15 patients in each group had bilateral arthroplasties (age range, 29-82 years; osteoarthritis, 77%). The two prostheses had a similar probability of survival at 5-6 years approximately (Charnley, 88%; Honnart Patel-Garches, 82%; *p*, not significant). More revisions were required in the Honnart Patel-Garches group over 5 years (18.7%, all for loosening, all but one causing mid-thigh pain) compared with the Charnley group (11%, five for loosening, no mid-thigh pain). A further five in the Honnart Patel-Garches group had a possible need for revision caused by mid-thigh pain (increasing the revision rate to 25%). Subsidence of more than 4 mm occurred in 5% (Charnley) and 33% (Honnart Patel-Garches). C-rated.

Olsson and colleagues, 1985³⁸

A total of 119 patients had either a cemented (Charnley, n = 61, mean age 67 years) or noncemented (Honnart Patel-Garches, n = 59, mean age 64 years) prosthesis implanted; 82% of patients had osteoarthritis. Clinical evaluation showed similar preoperative results but the Charnley prosthesis performed better at the 1-year assessment - Harris Hip Score and Limp, Charnley versus Honnart Patel-Garches, *p* < 0.001; maximal walking speed, Charnley versus Honnart Patel-Garches, p < 0.05 (twice as many patients with the Honnart Patel-Garches prosthesis required a device to assist them). A quantitative analysis of gait showed the latter group to have slightly better preoperative results but 1 year after surgery the Charnley group had greater improvement. No revisions were reported. C-rated.

Charnley versus porous-coated

Comment

In both of the studies summarised below relatively few porous-coated prostheses were assessed; the porous hips had only short- to mid-term follow-up compared with the Charnley hips. It is therefore very difficult to make conclusive judgements about relative performance. However, it would appear that porous hips have good short-term survival and, if this were to continue in the longer term, may be comparable to the Charnley.

Callaghan and colleagues, 1995³⁶

As part of a larger study, 330 Charnley hips (minimum follow-up of 20 years) and 89 Charnley hips in patients under 50 years of age (16–22 years follow-up) were compared with 100 PCA prostheses (minimum follow-up of 7 years). No patient details were given. In the Charnley groups, cup revision incidence was 10.6% in the 20-year follow-up group and 13% in the younger age group; loosening was 12.8% and 37%, respectively. Stem revision incidences in the two Charnley groups were 3.2% and 2.2%, respectively, with loosening reported in 4.3% and 6.1%, respectively. The porous-coated group had a cup revision incidence of 4% and a migration incidence of 5%, which included two revised cases. **C-rated**.

Hoffman and colleagues, 1994³³

This retrospective study involved a total of 1166 hips in 974 patients. Six surgeons (grade not specified) performed the operations in either a publicly-funded hospital (66%) or at a private clinic (34%). The average age of patients was

66 years, 89% had a diagnosis of osteoarthritis, there were slightly more men (54%) than women and 55% of operations were to the right side of the body. This section of the report refers to only a part of the overall study. There were 72 failures of the Charnley prostheses (n = 867) recorded, six caused by loosening; with an annual failure rate of 1.78% and a survival rate of 73% at 15 years. Neither the Harris-Galante (n = 105) nor the PCA prostheses (n = 38) had any revisions in approximately 3–4 years of follow-up. **C-rated.**

Charnley versus resurfacing

Comment

The results do not encourage the use of resurfacing hip prostheses.

Ahnfelt and colleagues, 1990¹⁴

The results of this retrospective study were taken from a Swedish multicentre registry. The patients' median age was approximately 64 years for women and 66 years for men; the main diagnosis was osteoarthritis. In all cases the hips had been implanted originally between 1979 and 1986 and had required revision. Survival without revision for loosening of the original THR was observed for various prostheses. Charnley hips had a 92% survival at 10 years (n = ?) whereas the Wagner resurfacing hip prosthesis had only 28% survival at 10 years – the worst result in the study. **C-rated**.

Cemented versus cemented (non-Charnley)

Comment

There are a great number of cemented prostheses available and, from the selection of studies below, it can be seen that results can vary considerably. There have been many design modifications over time, some apparently beneficial and others not. Some modifications, such as in the well-known case of the Christiansen prosthesis (see, for example, Ahnfelt *et al.*, 1990¹⁴), have had disastrous results. From these studies, prostheses such as Stanmore and T-28 appear to give good results over mid-term follow-up as does the Spectron/ITH combination in the short-term. The Spectron/Biofit and Lubinus SP hips may prove to have good outcomes but the numbers were too small to draw any conclusions. The Ritter study³¹ suggests that cemented all-polyethylene acetabular components perform better than cemented metal-backed components.

Ahnfelt and colleagues, 1990¹⁴

The results of this retrospective study were taken from a Swedish multicentre registry. The patients' approximate median age was 64 years for women and 66 years for men; the main diagnosis was osteoarthritis. In all cases the hips had been implanted originally between 1979 and 1986 and had required revision. Survival without revision for loosening of the original THR was observed for various prostheses. Eight out of ten cemented prostheses had results quoted for them. The observed survival ranged from 63% (Christiansen) to 89% (Stanmore) at 10 years and from 95% (Exeter) at 5 years to 93% (Lubinus) at 9 years. The Christiansen prosthesis gave very poor results compared with the other cemented types. (This 'trunnion-bearing device' was popular in the late 1970s in Sweden and in 5 years more than 5000 were implanted. By 1986, 1524 of them had been revised and survival analysis predicted that 200 more would require revision in the following 4 years). C-rated.

Ritter, 1995³¹

Four cemented hips were compared - 163 Müller, 642 T-28, and 319 MOSC hips with either an allpolyethylene cup or a metal-backed cup. The average follow-up time ranged from 8.9 years to 10.1 years. One surgeon performed all the operations. The mean ages of the patients, 66% of whom had osteoarthritis, ranged from 62 years (T-28) to 76 years (Müller); 13% of patients were lost to follow-up. Within 1 year of the operation, 20% of both the Müller and MOSC (metalbacked cup) failed, while only 9% of the MOSC (all-polyethylene) and 10% of the T-28 failed within the same time. Apart from metal-backing, the larger femoral head size of the Müller may also be implicated. An analysis of survival at 10 years showed the T-28 and MOSC (allpolyethylene) to be superior to the others: T-28 93% (75% at 17 years), MOSC (all-polyethylene) 90% (87% at 12 years), Müller 81% (56% at 17 years) and MOSC (metal-backed) 60%. C-rated.

Espehaug et al., 199539

In a Norwegian multicentre survey, 12,179 hips were followed-up for a mean of 3.2 years (maximum 6.4 years) at various hospitals. Approximately 50% of the patients were in the age range 65–74 years (diagnosis was not given). The 5-year failure rates for the prostheses ranged from 7.33% for Müller type hips (n = 116) and 4.96% for Spectron/Lubinus combinations (n = 302) to 0.85% for Spectron/ITH combination (n = 1034) and Spectron/Biofit (n = 152); Lubinus SP hips (n = 129) required no revisions. **C-rated.**

Non-Charnley cemented versus ceramic

Comment

There were too few results (all from C-rated studies with small numbers of patients) to make convincing statements regarding the relative benefits of ceramic and cemented. Ceramic prostheses were originally designed to reduce wear and one comparative study (Zichner & Willert, 1992,⁴⁰ in which the same surgeons performed all operations) showed this to have been achieved in the hips assessed, together with a lower revision rate than for cemented prostheses. The short-term results compared with cemented prostheses appear to be worth investigating further.

Zichner and Willert, 1992⁴⁰

A Müller-type endoprosthesis was inserted into 354 hips in 313 patients between 1970 and 1980: 149 with a Protasul-2 ball (average follow-up 66 months); 105 with Protasul-10 ball (average follow-up 46 months); 100 with a ceramic ball (average follow-up 73 months). All the prostheses were implanted at the same clinic by the same surgeons using the same technique. As a result of loosening, 10% Protasul-2 and 4.8% Protasul-10 prostheses were revised compared with 2% of the ceramic types. Displacement rates were also assessed: 30% of the non-revised Protasul-2 ball hips had a displacement rate of > 0.2 mm/year, 8% with a displacement rate of > 0.3 mm/year; 20% of the non-revised Protasul-10 ball hips had a displacement rate of > 0.2 mm/year. However, 95% of all ceramic ball prostheses had a displacement rate of < 0.02 mm/year, with 63% having a displacement rate of < 0.1 mm/year. C-rated.

Schuller and Marti, 1990⁴¹

Weber type prostheses with metal heads were inserted in 48 patients at a teaching hospital and compared with 46 similar prostheses with ceramic heads inserted at a private clinic. The mean follow-up was 10 years (range 9–11 years) for patients with osteoarthritis (age range 48–78 years). In each group, 33 patients were available for subsequent analysis. Wear for the metal-head hips was 0.96 mm and for the ceramic hips 0.26 mm (p < 0.001). Of the cemented hips, 9% were revised because of loosening, 12% were loose; 6% of the ceramic hips were revised because of loosening and 9% were loose (p, not significant). No analysis assessing the possible influences surrounding the different types of hospital was undertaken. C-rated.

Hoffman and colleagues, 1994³³

This retrospective study involved a total of 1166 hips in 974 patients. Six surgeons (grade not specified) performed the operations either at a publicly funded hospital (66%) or at a private clinic (34%). The average age of the patients was 66 years, 89% had a diagnosis of osteoarthritis, there were slightly more males (54%) than females, and 55% of operations were to the right side of the body. This section of the report is only part of the overall study. Four types of cemented prostheses were mentioned in the study but survival information was only given for one: Müller (n = 92) – 26 failed (23 were loose), annual failure rate was 6.93%, and 11-year survival rate 63%. However, this result is confounded by the poor results of one surgeon. The ceramic prosthesis, Autophor (n = 35), had a failure rate of 15% in 3 years (approximate annual failure rate of 5%). C-rated.

Non-Charnley cemented versus HA-coated

Comment

The follow-up period for both these C-rated studies is very short; hence, the results should be treated cautiously. The second study used speciallydesigned prostheses.¹² The authors of both studies suggested that HA-coated models had more stable early fixation than cemented models. No difference in early pain scores can be substantiated. Freeman and Plante-Bordeneuve¹² suggest that there is an association between pain and the extent of early migration on radiological assessment, and that HAcoated components perform better in this respect, at least in the early postoperative period. This may be in contrast to the comparison of Charnley with HA-coated designs (see page 22) in which no differences were demonstrated. Longer-term assessments involving greater numbers of patients are required.

Karrholm and colleagues, 1994⁴²

A computer program was used to randomly allocate the 64 patients (age range 58–66 years) in this RCT. The patients were stratified by various characteristics. The hips had the Ti-Fit femoral component inserted with a press-fit acetabular component by one of four surgeons at one of two hospitals. The femoral stems were inserted with either cement (n = 20) or an HA-coating (n = 23). After 2 years the cemented stems had subsided more than the HA-coated stems (p = 0.002). The HA-coated components also rotated less compared with the cemented stems (p = 0.03). The Harris Hip and Pain Scores did not differ significantly between the groups, although the small sample sizes make this result tentative. There were no revisions within the 2 years of the study. **C-rated.**

Freeman and Plante-Bordeneuve, 1994¹²

The prosthesis in this study was specially designed to allow measurement of vertical migration. The THRs were either cemented (55 hips in 54 patients, 91% with osteoarthritis, 69% female, age range 57-83 years) or HA-coated (34 hips in 34 patients, 88% with osteoarthritis, 41% female, age range 33–76 years). The amount of migration was assessed at 2 years: cemented hips (n = 55) had a mean of 0.55 mm, while those hips with no pain (n = 52) had migrated 0.38 mm on average; all HA-coated hips (n = 34) had migrated on average 0.4 mm, the same as those hips with no pain (n = 34). At a minimum followup of 5 years, 7.9% of the cemented prostheses were loose. At 4-year follow-up no HA-coated hips required analgesia or had been revised. C-rated.

Non-Charnley cemented versus hybrid

Comment

As with the Charnley versus hybrid comparisons, hybrid prostheses appear to survive in the following studies as well as, if not slightly better than, cemented hips in the short term but it is not yet possible to comment on longer follow-up results. There may be the potential for hybrid prostheses to equal or improve on the results of cemented hips such as those reported here. As both of these studies were C-rated, higher quality studies are also required of this type of comparison.

Wixson and colleagues, 199143

A total of 197 hips were implanted into 176 patients by two surgeons and, after a mean follow-up period of 2.8 years (maximum 4 years) 144 hips were available for analysis. The mean age of patients, 60% of whom were female, was 61 years; 65% had osteoarthritis and 15% rheumatoid arthritis. Various types of cemented stems were used along with either cemented cups (PCA, TiBac, Harris) or porous-coated (PCA, Harris-Galante, APR). The various combinations were categorised as cemented or hybrid as appropriate. Two cemented hips (3.8%) were revised because of loosening while one hybrid (3.7%) was revised (but not for loosening). Of the cemented cups, 12% had migrated or changed position compared with 3% of porous cups (*p* = ?). **C-rated.**

Callaghan and colleagues, 1995³⁶

As part of a larger study, IOWA prostheses, using second generation cementing techniques (n = 187, minimum follow-up 10 years), were compared with 130 hybrid hips (Harris-Galante type 1 cup + IOWA cemented stem, 5-year follow-up) and 61 similar hybrids were used as revisions (minimum follow-up 5 years). No patient details were given. In the cemented group, cup loosening occurred in 24.5% of patients (metal-backed 17%, allpolyethylene 30%) and stem loosening in 1.2%. This is in contrast to the hybrid groups where no revisions (or re-revisions) were reported and only one migration in the revision group occurred; however, the follow-up period was only 5 years or more compared to 10 years or more for the cemented group. Wear rates were also assessed in this study with the Harris-Galante cups (28 mm head) having less wear than the other groups but, unfortunately, no details were given. C-rated.

Non-Charnley cemented versus modular

Comment

The fact that neither clear results nor patient details were given for the Osteonics/DuPuy model in the study below makes commenting on it difficult. The cemented hips gave fairly typical results for this type of prosthesis and appear to be superior to the modular forms but a better evaluation is required.

Chmell and colleagues, 199544

Three surgeons performed all the operations in this study. No details are given about the patients involved. Three cemented prostheses were used: Aufranc-Turner (n = 778); T-28 (n = 823) and Osteonics non-modular stem with cemented cup (n = 329); these were compared with three modular prostheses (as specified by the authors): Osteonics modular stem and cemented cup (n = 233); DePuy Profile modular stem with ACS modular cup (n = 203) and Osteonics modular stem with either Osteonics or DePuy Duraloc modular cup (n = ?). The percentages needing revision for loosening in the cemented groups ranged from 2.1% of the Osteonics hips after an average follow-up of 7.5 years to 22% of the Aufranc-Turner hips after an average follow-up of 12 years, the majority of these being after the first 6 years. In the modular group, 3% of the Osteonics modular stem (with the same cemented cup as before) were revised within 6 years and 12% needed revision in the DePuy Profile/ACS hip because of linear wear or fracture (all but two of

the 15 had a polyethylene thickness of less than 6 mm). No details were given for the Osteonics/ DePuy hip, except that they "have not been associated with the catastrophic failure rate seen in the ACS cups". **C-rated.**

Non-Charnley cemented versus press-fit

Comment

The results from the three studies selected below are conflicting. Two (one of them A-rated) showed more problems with the press-fit than with the cemented hips. However, in the remaining study,^{45,46} although the press-fit stem showed evidence of subsidence it was the cemented cups which were deemed to be loose, although this was at only 4-year follow-up. Overall, cemented types of prosthesis would appear to be superior to press-fit.

Godsiff and colleagues, 1992²⁵

This RCT compared 30 cemented with 28 uncemented femoral components (Ring prosthesis) in patients, age range 55-74 years, with osteoarthritis of the hip. Both patients and the nonorthopaedic clinical assessor were blinded and surgery was by one of two surgeons. At 2 years both groups (n = 47) reported similar pain incidence, the press-fit group having had more pain at 4 and 12 months. By 2 years, 96% (cemented) and 62% (uncemented) of patients did not require walking aids (p = 0.01 - 0.05). Preliminary results indicated cemented to be superior to pressfit; however, because of unacceptable levels of femoral breakages at 3-5 years, the authors withdrew the Ring prosthesis. These failures may have been due in part to design and manufacturing factors, as reported in a Safety Notice issued by the Department of Health Medical Devices Agency (MDA SN 9520) in August 1995. The design has subsequently been modified. A-rated.

Bourne and colleagues, 1995;⁴⁵ Rorabeck and colleagues, 1996⁴⁶

All patients in this RCT were operated on or supervised by two senior surgeons using the Mallory Head prosthesis, either cemented or press-fit. A total of 250 patients were originally recruited from a group with an age range of 18–75 years and were stratified by age and surgeon. Diagnosis was osteoarthritis of the hip. Clinical results had a 5-year follow-up period (n = ?) and radiographic analysis a 4-year follow-up (n = 147). Patients and clinical observers were blinded. All clinical assessments (e.g., Harris Hip Score, d'Aubigne Score and Sickness Impact Profile, among others) were almost identical for each group both pre- and postoperatively. There was no subsidence in the cemented stems but 14% of press-fit stems subsided by 3–5 mm. No revisions were required within 4 years and no press-fit components or cemented stems were loose; however, 26% of the cemented cups were described as definitely or probably loose. **C-rated.**

Krismer and colleagues, 199147

Uncoated RM cups were paired with Müller stems to form the press-fit hip and 160 from 173 (mean age of patients 57 years, average follow-up 5.3 years) were assessed and compared with 263 from 309 Müller prostheses (mean age of patients 63 years, average follow-up 6.1 years). The diagnosis in 75% of patients was primary coxarthrosis. None of the cemented prostheses migrated during the study period but 25% of the press-fit migrated between 2.1 and 16 mm. After 7–8 years, 12% of the press-fit hips had been revised and 40% were loose compared with 4% and 15%, respectively, of the cemented hips. **C-rated**.

Non-Charnley cemented versus porous-coated

Comment

Ten comparisons of these types of prosthesis have been reviewed overall. In only one of the three papers selected below was an attempt made to compare the two types of prosthesis at the same time after surgery. In one study with medium-term follow-up and a fair sample size, Callaghan and colleagues³⁶ suggested that the cemented acetabular component performed better than the porouscoated but that the porous-coated stem was better than the cemented. As with the Charnley comparisons, porous-coated types appear to have good short-term survival results which need to be followed further.

Callaghan and colleagues, 1995³⁶

As part of a larger study, IOWA prostheses, using second generation cementing techniques (n = 187, minimum follow-up period 10 years) were compared with 100 PCA prostheses (minimum follow-up 7 years). No patient details were given. In the cemented group, cup loosening occurred in 24.5% of patients (metal-backed 17%, all polyethylene 30%) and stem loosening in 1.2%. The PCA prostheses had a cup revision incidence of 4% and a migration incidence of 5%, which included two revisions. **C-rated.**

Hoffman and colleagues, 1994³³

This retrospective study involved a total of 1166 hips in 974 patients. Six surgeons (grade not specified) performed the operations at either a publicly funded hospital (66%) or a private clinic (34%). The average age of patients, of whom 89%had a diagnosis of osteoarthritis, was 66 years; there were slightly more males (54%) than females, and 55% of operations were to the right side of the body. This section of the report forms only a part of the overall study. Four types of cemented prostheses are mentioned in the study but survival information is only given for one: Müller (n = 92) – 26 failed (23 were loose), the annual failure rate was 6.93%, and the 11-year survival rate 63%. However, this result is confounded by the poor results of one surgeon. Neither the Harris-Galante (n = 105) nor the PCA (n = 38) prostheses had any revisions in approximately 3-4 years of follow-up. C-rated.

Hearn and colleagues, 1995⁴⁸

A total of 36 consecutive patients underwent primary cemented THR (Charnley, Dual Lock or Pennsylvania Total Hip) followed by primary porous-coated THR (Trilock or Taperloc) of the contralateral hip (total number of hips, 72). Of these, 60 were assessed after 8.1 years (cemented hip) and 3.0 years (porous hip) ('same interval' data for the cemented hips were also compared with the porous data at 3.6 years). The patients' age range was 21-82 years, 92% had diagnoses of osteoarthritis and 8% of rheumatoid arthritis. Preoperative pain levels differed (cemented 3.1, porous 2.5, p = 0.002), as did the range of movement measurements at the same interval of follow-up (cemented 5.1, porous 5.6, *p* = 0.002). There was no migration or subsidence, and there were no revisions. One cemented stem was probably loose but no porous components were loose. C-rated.

Non-Charnley cemented versus resurfacing

Comment

All three papers summarised below report resurfacing prostheses to be inferior to all of the cemented hips with which they were compared. Thus resurfacing prostheses cannot be recommended as an alternative to cemented THRs.

Reigstad and colleagues, 198649

A total of 155 Müller and 149 ICLH prostheses were implanted into 231 patients (age range 60–79 years) by 13 surgeons. All patients were diagnosed with osteoarthritis of the hip and had a mean follow-up of 48.5 months. No Müller hips were revised compared with 8.7% ICLH (p < 0.001) and, in addition, one component (0.6%) was loose compared with 12 (8%), respectively. Postoperatively the Müller group had consistently higher scores than the ICLH group on all three modified Merle d'Aubigne and Postel parameters and total hip function. The level of significance reached by 1 year in 3/4 parameters was p < 0.001. **C-rated**.

Ritter and Gioe, 1986⁵⁰

Bilateral hips in 50 patients were replaced with one cemented T-28 prosthesis and one Indiana conservative resurfacing hip using the same anaesthetic; 45 (90%) of these patients were followed-up for a minimum of 5 years. The mean age of the patients was 62 years (range 21–87 years) and 79% were diagnosed with osteoarthritis. There was no difference in the level of pain in the non-revised hips, as recorded by the Hospital for Special Surgery Rating System. Two (4.4%) cemented hips were revised (none were loose) and 15 (33%) resurfacing hips were revised (these patients were younger, average age 55 years). **C-rated.**

Ahnfelt and colleagues, 1990¹⁴

Results from this retrospective study were taken from a Swedish multicentre registry. The patients had an approximate median age of 64 years for women and 66 years for men, and a main diagnosis of osteoarthritis. In all cases the hips had originally been implanted between 1979 and 1986 and had required revision. Survival without revision for loosening of the original THR was observed for various prostheses. Eight out of ten cemented prostheses had results quoted for them. The observed survival ranged from 63% (Christiansen) to 89% (Stanmore) at 10 years and from 95% (Exeter) at 5 years to 93% (Lubinus) at 9 years. This is in comparison to the Wagner resurfacing hip prosthesis which had only 28% survival at 10 years, the worst result in the study. **C-rated.**

Ceramic (cemented) versus ceramic (cementless)

Comment

No statistical analysis was performed on the revision figures in the paper below but, given the difference in follow-up time, the results may be roughly equal, suggesting no difference at short-term follow-up between the cemented and cementless methods of fixation of ceramic hips.

Riska, 1993⁵¹

The Ceraver Osteal aluminia on aluminia prosthesis was implanted with either a cemented ceramic cup (n = 143, mean follow-up period 6.7 years) or an uncemented ceramic cup (n = 112, mean follow-up period 3.6 years). One surgeon performed the operations on the patient group who had a mean age of 62 years and 73% of whom had a diagnosis of osteoarthritis. Prostheses with the cemented cup had 16 revisions (11.2%) and 14 were loose. Seven revisions (6.3%) were required in the uncemented cup hips and two were loose. **C-rated.**

Ceramic versus porous-coated

Comment

Very small numbers of ceramic prostheses were included in the only study permitting comparison of these two types. Strong conclusions cannot be drawn, although the results suggest that ceramic prostheses are unlikely to be superior to porouscoated over the short term.

Hoffman and colleagues, 1994³³

Study details are given above (page 23). The ceramic prosthesis (Autophor, n = 35) had a failure rate of 15% in 3 years, giving an approximate annual rate of 5%. Two different porous-coated THRs were included in the study: Harris-Galante (n = 105) and PCA (n = 38). Both had a follow-up period of roughly 3–4 years (compared with approximately 6 years for the ceramic prosthesis) and neither design had had any failures in this time. **C-rated.**

HA-coated versus press-fit

Comment

From the two studies selected from the five available, HA-coated prostheses appear to be more stable than press-fit in the (very) short term, being associated with less migration/subsidence and pain and possibly with greater mid-term survival.

Huracek and Spirig, 1994⁵²

Forty pairs of patients were retrospectively matched for various aspects from 127 possible cases. One surgeon inserted all the hips either with an HA coating or without (press-fit). All patients had primary osteoarthritis, their average age was 71 years and average length of follow-up was 4.1 years. The occurrence of pain was assessed: 59.3% of HA hips had no pain compared with only 22.5% of press-fit hips (*p* < 0.0016). No HA-coated cups showed signs of migration and 7.5% of HA-coated stems subsided. In the press-fit hips, 32.5% of cups migrated by 5 mm or more and 30% of stems subsided. There were no revisions or loose components in either group. **C-rated.**

Moilanen and colleagues, 199653

The SLF cup (together with a Freeman cemented or uncemented stem) was inserted either with an HA-coat or without (press-fit). The mean age of the patients given an HA-coated cup was 59.7 years (74% with osteoarthritis, 2.3 years follow-up) while those with press-fit cups had a mean age of 62.6 years (95% with osteoarthritis, 3.4 years follow-up). There was no difference in mean migration rate between the two groups but the press-fit group had more radiolucent lines associated with them (27%) than did the HAcoated group (6%, p < 0.05). Two revisions were required in the HA-coated hips within 7 months of the operation, neither being caused by loosening; no hips were replaced from the press-fit group. C-rated.

HA- versus porous-coated

Comment

Both of these studies have only a short follow-up period. The porous-coated hips seemed to have more subsidence and did not initially fix as well as the HA-coated hips. How this would affect the longer term clinical and survival outcomes is unclear at the present time. One study suggests there are no differences in hip scores, including pain, between the two types in the early post-operative period. This is echoed by one observational study.⁵⁴ Further investigation of the two types of coating is required.

Karrholm and colleagues, 199442

A computer program was used to randomly allocate the 64 patients (aged 58-66 years) in this RCT. The patients were stratified by various characteristics. The hips had the Ti-Fit femoral component inserted with a press-fit acetabular component by one of four surgeons in one of two hospitals. The femoral stems were inserted with either an HA-coating (n = 23) or were porouscoated (n = 21). After 2 years the porous-coated stems had subsided more than the HA-coated (p = 0.02). The Harris Hip and Pain Scores did not differ significantly between the groups. Pain or discomfort in the thigh was reported (HAcoated, n = 5; porous-coated, n = 8; p = ?). There were no revisions within the 2-year period. C-rated.

McPherson and colleagues, 1995⁵⁵

HA-coating was added to a prosthesis, this time an APR-I hip, to perform this study. Data were collected prospectively but the study groups were selected retrospectively. From 230 patients, 42 pairs were matched, giving an average age of approximately 56 years (the diagnosis of the patients is not given but was used during the matching process). Using a modification of the DeLee-Charnley Fixation Score, the authors suggest that fixation was better in the HA-coated hips (p = 0.002) after a minimum follow-up period of 3 years – porous-coated hips: 62% Grade IA, 33% Grade IB; HA-coated hips: 93% Grade IA, 7% Grade IB. The mechanical failure rate for both groups was 5% - one revised HAcoated hip and one HA-coated and two porouscoated hips loose. C-rated.

Hybrid versus porous-coated

Comment

All three papers found hybrid prostheses to be superior to porous-coated over the short term, especially as regards the stem component. The studies reported thigh pain to be more closely associated with the porous-coated hips as were movement and the need for revision.

Wixson and colleagues, 199143

Originally 197 hips were implanted into 176 patients by two surgeons, and 144 hips were available for analysis after a mean follow-up time of 2.8 years (maximum 4 years). The mean age of the patients, 60% of whom were female, was 61 years; 65% were diagnosed with osteoarthritis, 15% with rheumatoid arthritis. Various types of porous-coated cups (PCA, Harris-Galante, APR) were used together with either cemented stems (PCA, SixTi/28, ATS, Harris Design 2 and CHD) or porous stems (PCA). The various combinations were categorised into hybrid or porous, as appropriate. Thigh pain was recorded at 3 years: cemented stem 3%, porous stem 13%; p < 0.05. There was no subsidence of the cemented stems while 5% of the uncemented ones changed position (as did 3% of the cups). More revisions occurred in the porous hips (7.7%, 4/5 loose)than the hybrid (3.7%, none loose). C-rated.

Goetz and colleagues, 1994⁵⁶

One surgeon performed 255 operations on patients with an age range of 40–71 years, 95% of whom had a diagnosis of osteoarthritis. Retrospectively 82 hips (in 74 patients) were matched and compared, with an approximate 6-year follow-up period. All had a Harris-Galante cup with either a Harris-Galante stem or a Harris Precoat (cemented) stem. Osteolysis was assessed in both groups: 29% of the porous hips showed osteolysis (five were loose) while the hybrid hips showed none (p < 0.0002; there was no relationship between femoral head size and osteolysis). A total of 12% of porous stems were revised (4/5 were loose, eight had subsided or migrated). None of the hybrid hips required revision (p < 0.02), all were stable with no radiolucent lines. None of the cups in either group had migrated or been revised. **C-rated**.

Maloney and Harris, 199057

Precoated cemented stems and Harris-Galante cups were compared to Harris-Galante prostheses in a retrospectively matched study of 25 pairs of hips (selected from a group of 136 hips). One surgeon performed the operations and follow-up was for 2.5-3 years. The patients' age range was 54-69 years (average 61-62 years) and 96% had osteoarthritis. Postoperative Harris Hip Scores differed between the groups (hybrid 96, porous-coated 84; p < 0.02) as did thigh pain (hybrid 0, porous-coated 20%; p = ?). Migration had occurred in 20% of the porous group stems, but not the hybrid stems (there were no radiolucent lines or migration associated with the cups of either group). Of the porous group, 16% required revision, 3/4 due to migration. No hybrid hips were revised. C-rated.

Modular versus modular

Comment

Comments on this one study are difficult to make as not all the data are given for the different prostheses, nor are any patient details given. The only possible comment is that the hip which combined a modular stem with a cemented cup (classed as a 'modular' type by the authors) faired better than the fully modular prosthesis on which data were given.

Chmell and colleagues, 199544

Three surgeons performed all the operations in this study. No details are given about the patients. Three modular prostheses were used as a part of this study: Osteonics modular stem and cemented cup (n = 233); DePuy Profile modular stem with ACS modular cup (n = 203) and Osteonics modular stem with either Osteonics or DePuy Duraloc modular cup (n = ?). Of the Osteonics modular stem, 3% were revised within 6 years and the DePuy Profile/ACS hip needed revision in 12%

caused by liner wear or fracture (all but two of the 15 had a polyethylene thickness of less than 6 mm). No details were given about the Osteonics/DePuy hip, except that they "have not been associated with the catastrophic failure rate seen in the ACS cups". **C-rated.**

Press-fit versus press-fit

Comment

Both studies were C-rated and only one had the basic minimum numbers of patients (see page 14). It would appear that the material from which the prostheses are made might influence the results. Further work is needed to assess this more fully but, given the poor results of the press-fit types compared with other prostheses, this is probably not worthwhile.

Schreiber and colleagues, 1993²⁰

The Balgrist prosthesis was used in this study with either an outer split ring of high-density polyethylene (61 patients had a thin (6 µm) coating of titanium on the outer surface) or of titanium alloy. The study was retrospective. The patients' age range was 23–76 years (average approximately 55 years) but diagnosis and the number of surgeons involved is unknown. From 717 hips, 606 were assessed after 4.5 years (polyethylene) or 1.3 years (titanium). During the follow-up to this study, 13% of primary and 21% of revised polyethylene types were revised, as were 0.7% primary and 5% revised titanium alloy types (p=?). **C-rated.**

Nashed and colleagues, 199558

This is included as part of a larger study in which cemented prostheses were compared with the two press-fit prostheses mentioned here. The retrospective study involved one surgeon; the patients had an approximate mean age of 50-51 years, with diagnoses of osteoarthritis and rheumatoid arthritis in 53% and 16%, respectively. The press-fit hips were both BIAS prostheses with a metal-backed cup, one with a titanium head (n = 15) and the other with a cobalt-chrome head (n = 74). The follow-up period was approximately 6 years. Osteolysis occurred in 87% of the hips with titanium-heads (87% stem, 40% cup) and in 24% with cobalt-chrome heads (22% stem, 14% cup). The incidence of osteolysis was statistically higher in the titanium group than in any other group (including the cemented hips). Hips with osteolysis were found to be more likely to require revision than those without osteolysis in the overall study (*p* < 0.001). **C-rated.**

Press-fit versus porous-coated

Comment

In the one study in which this comparison was included, the porous cup performed better than the press-fit cup. This would appear to be consistent with other studies comparing either porous or press-fit to other types where press-fit designs are uniformly inferior to other types of prosthesis.

Pupparo and Engh, 198959

In this prospective study, AML stems were combined with either an S-ROM Anderson cup (smooth-threaded) or an S-ROM Super cup (porous-threaded). One surgeon, of unknown grade, performed the operations. The ages of the patients were not stated but 86% of them had a diagnosis of osteoarthritis. Approximately 67% of the hips originally recruited were available for follow-up assessment at 2–3 years. Of the hips with an Anderson cup, 29% were classed as unstable and nine had migrated by a mean of 5.5 mm, whereas the hips with a Super cup showed no migration and were all classed as stable (p < 0.001). No Super cup hips were revised but six of the Anderson cups were, all caused by loosening (p =?). **C-rated.**

Porous-coated versus porous-coated

Comment

The three prostheses used in the study summarised below gave similar results over the short term. However, the number of patients was small and the ratio of disease types unusual compared with the vast majority of comparative studies used in this report. This being the case, further work is required involving larger numbers to gauge if this is a true result or if the different prostheses do differ in any way.

Hwang and Park, 199560

Three types of porous-coated prosthesis are compared in this prospective study: AML (n = 90, mean follow-up period 5.2 years); PCA (n = 117, mean follow-up period 4.7 years); Harris-Galante (n = 63, mean follow-up period 3.8 years). The age range of the patients was 20–86 years (approximate mean 48 years). The diagnosis for this group of patients was very different from most other studies as the main diagnosis was of avascular necrosis (66%) with osteoarthritis in 18%. One surgeon was involved in replacing the hips. Approximately 19% of each group had thigh pain. Stem subsidence ranged from 0–8 mm, with an approximate average of 2.1 mm, and was similar for all groups, as was the number with subsidence of 3 mm or more (AML 10%, PCA 13.7%, Harris-Galante 12.7%). Cup migration did not differ between the groups (all approximately 4.1% 0 and no revisions were reported. **C-rated.**

Porous-coated versus resurfacing

Comment

32

The study summarised here concentrates on heterotopic bone formation and not on the usual outcome measures. Although this study (with few patients and a higher number of patients with avascular necrosis than most studies) showed no difference between the two types of prosthesis, resurfacing replacements are not recommended for the usual indications for THR, because of the results shown in the comparisons above.

Duck and Mylod, 1992⁶¹

The original population from which the study group was taken was not stated but the study concentrated on 66 hips in 55 patients with a range of diagnoses, such as 34.5% osteoarthritis and 36.4% avascular necrosis. The average age of the group was 60 years (range 33-76 years). As part of a larger, retrospective study, AML porous-coated hips were compared to resurfacing prostheses (TARA and Indiana Conservative hip) 3 years after the operation (number of surgeons performing surgery unknown). The study concentrated on the occurrence of heterotopic bone formation: 59% of the uncemented total hips had heterotopic as did 56% of the resurfacing hips. The authors concluded that there was "no significant correlation between the type of procedure and the percentage bone formation". C-rated.

Chapter 9

Results of selected observational studies

The summaries presented in this chapter should be read in conjunction with the more detailed data tables for each type of prosthesis in the appendix to this report. The best available studies of each prosthesis type have been selected for inclusion here, as indicated.

- A or B-rated by the reviewers
- cohort size of > 200 hips followed-up
- survival or revision rate data presented.

Non-Charnley cemented designs

The studies presented in *Table 19* fulfil the same criteria as the Charnley studies presented in *Table 18.*

Comment

As a group, these selected studies of cemented prostheses show that rates of early survival (up to 10 years) are generally very good for most models;

Cemented designs

Charnley

The studies summarised in *Table 18* fulfill the following criteria:

TABLE 18 Selected studies of the Charnley cemented prosthesis

| Study | Number of hips (follow-up period, years) | Age (years) | Results |
|--|--|----------------|---|
| Dall, et <i>al.</i> , 1993 ⁶² | 811 (10–12) | mean 60 | 87% survivorship at 10–12 years (revision rate 8%) |
| Eftekhar, et <i>al.</i> , 1986 ⁶³ | 499 (> 10) | mean 62 | Re-operation 2.2% (+1.2% pending) |
| Garcia-Cimbrelo & Munera, 1992 ⁶⁴ | 680 (18) | mean 56 | 81% survivorship at 18 years (91.6% at 10 years) |
| Hamilton & Joyce, 1986 ⁶⁵ | 230 (6) | 86% over 50 | Revision rate for aseptic loosening: stem 0.0%, cup 0.7% |
| Hamilton & Gorczyca, 1995 ⁶⁶ | 224 (10 +) | mean 58 | Stem revision rate 6.3%; cup revision rate 6.7% (12.5% cup migration rate) |
| Joshi, et <i>al.,</i> 1993 ⁶⁷ | 218 (10–24) | mean 32 | Stem revision rate for aseptic loosening: 3% at 10 years, 14% at 20 years; cup revision rate: 4.5% at 10 years, 16% at 20 years (osteoarthritis risk revision 20% at 10 years, 49% at 20 years) |
| Kobayashi, et <i>al.</i> , 1994 ^{68,69} | 326 stems, 328 cups (13) | mean 58 | Stem revision rate 1.2% (4.9% failure); cup revision rate 7.4% (17% failure) |
| Madey, et <i>al.</i> , 1997 ⁷⁰ | 356 (15) | mean 62 | Revision rate for aseptic loosening 11% at 15 years (stem 2%, cup 10%) |
| Neumann, <i>et al.,</i> 1994 ⁷¹ | 241 (15–20) | median 62 | Probability of revision 10.7% at 20 years |
| Older & Butorac, 1992 ⁷² | 388 (17–21) | mean 68 | Revision rate 6%; 89% survivorship at 20 years |
| Skeie, et al., 1991 ⁷³ | 629 (10–15) | mean 66 | 92% survivorship at 13 years (7% revised) |

revision rates at a minimum of 10 years in age groups from mid-50s to mid-60s range from about 2% to about 13%. Revision rates in the one series of young patients (by Joshi and colleagues)⁶⁷ are moderate for such a group of young patients with a diagnosis of osteoarthritis. Given the unknown part played by potentially confounding factors, comparisons between prostheses on the basis of these observational studies can be made only tentatively and by treating the reported survival rates as estimates requiring wide confidence intervals. Taking this into account, the Howse, Exeter and Lubinus models appear to bear comparison with the Charnley at medium term (10–15 years) follow-up.

Uncemented designs

Porous-coated

Only four of the reviewed studies of cementless porous-coated technology fulfil the same criteria as the 17 studies of cemented prostheses summarised in *Tables 18* and *19*. Three of these are by the same group of authors, Engh and colleagues,^{80–82} and present results for the same component, the AML straight stem. The results from the most recent of these studies⁸² are summarised in *Table 20* together with those from the A-rated study by Owen and colleagues,⁸³ in which more than 200 hips were followed up, and from the only other study with 10-year results (Sotereanos *et al.*, 1995).⁸⁴

The study by Owen and colleagues⁸³ records a steep decline in survival of cups between years 6

TABLE 19 Selected studies of cemented non-Charnley prostheses

and 9, especially in younger patients, which is attributed to severe polyethylene wear caused by the use of the large (32 mm) stem head size. Engh and colleagues' results⁸² are good for medium-term follow-up, especially when the relatively young mean age of the study group is taken into account. With the exception of these two studies and that by Holman and Tyer,⁸⁵ the numbers of hips followed up with porous-coated prostheses are very modest, with the majority being about 100 and many being fewer than this.

The results at 10 years appear to bear comparison with the cemented models for the same follow-up period, especially when account is taken of the relatively lower average age of the patient groups implanted with porous-coated models compared with those receiving cemented models.

The AML and PCA models are those for which results have been most frequently published (of the reviewed observational studies: PCA, 13 studies; AML, 8; Harris-Galante, 6). Sotereanos and colleagues' results for the AML stem are exceptionally good.⁸⁴

Thigh pain is an issue for porous-coated implants. In the studies reviewed, reports of its prevalence range from about 2% to about 25% at 2–7 years' follow-up. Several studies report prevalences of about 25%, including in non-loose stems.

The amount of porous-coating on stem components is an issue. The majority of

| Study | Prosthesis type | Number of hips (follow-up period, years) | Age (years) | Results |
|---|--------------------|---|----------------|--|
| August, et al., 1986 ⁷⁴ | McKee-Farrar | 230 (10–22) | mean 60 | 91% survivorship (revision) at 10 years, 84% at 15 years, 27.5% at 20 years |
| Bryant, et <i>al.,</i> 1991 ⁷⁵ | Ring | 253 (20) | mean 63 | 60% survivorship (revision) |
| Fowler, et <i>al.,</i> 1988 ⁷⁶ | Exeter | 241 (11–16) | mean 67 | Total mechanical failure 11% |
| Ohlin & Onsten, 1990 ⁷⁷ | Lubinus | 202 (3–6) | median 68 | Revision rate 3% for aseptic loosening |
| Partio, et <i>al.</i> , 1994 ⁷⁸ | Lubinus | 444 (8–12) | mean 64 | Revision rate 11.5%; 87% survivorship at 10 years |
| Roberts, et <i>al.</i> , 1987 ⁷⁹ | Howse | 265 (10–15) | mean 63 | 90% survivorship (revision) at 10 years, 80.8% at 15 years |

| Study | Prosthesis type | Number of hips (follow-up period, years) | Age (years) | Results |
|--|--------------------|---|----------------|--|
| Engh, et <i>al.,</i> 1997 ⁸² | AML stem | 223 (minimum 10) | mean 55 | 85% stem survivorship at 12 years |
| Owen, et al., 1994 ⁸³ | PCA | 241 (2–9; mean 5) | mean 47 | 57% survivorship at 7 years (including recommendation for revision) |
| Sotereanos, et <i>al.</i> , 1995 ⁸⁴ | BIAS and AML stems | 121 and 166 (10 and 8) | mean 53–54 | BIAS: revision rate 4.1% at 10 years; survivorship 95.4% at 11 years; AML: revision rate 0.6%; survivorship 99.3% at 9 years |

TABLE 20 Selected studies of uncemented porous-coated prostheses

porous-coated implants, where the information was given, had the coating on the proximal part of the stem plus the cup. In a comparative study on animal models⁸⁶ (not appraised in this review), it is suggested that total circumferential coating is associated with more bone loss than partial coating.

HA-coated

Three studies met the criteria of being A- or Brated, including more than 200 hips and having survivorship results reported.^{54,87,88} These are summarised in *Table 21* together with the two studies with the longest follow-up.^{89,90}

Of the nine HA-coated studies summarised in the appendix, five report on the American Osteonics Omnifit components, thought to be the most widely used HA-coated model internationally.⁹¹ It is clear that the numbers of patients/hips and lengths of follow-up periods are insufficient to draw

TABLE 21 Selected studies of uncemented HA-coated prostheses

even tentative conclusions about the performance of this technology on the basis of survival data. The evidence for early postoperative pain associated with this type of technology suggests mild to moderate thigh pain in between 0% and about 5% of patients at 2–5 years' follow-up. This is a relatively good result in comparison to the results for porous-coated implants.

Uncoated press-fit

Only one study in this category is A- or B-rated, follows-up more than 200 hips and presents survival results.⁹² This study of Mathys 'isoelastic' cups reports a high level of revision for aseptic loosening, mostly occurring after at least 8 years of implantation. The component was abandoned. Two of the other studies reviewed reported on the Mathys RM isoelastic components.^{93,94} The first⁹³ also showed relatively poor results for the uncoated cup (although the ages of patients were not reported)

| Study | Prosthesis type | Number of hips (follow-up period, years) | Age (years) | Results |
|---|----------------------|---|--------------------------|---|
| Tonino, et al., 1995 ⁸⁷ | ABG | 222 (minimum 2, mean 2.4) | mean 63 | Revision rate (mechanical) 1.4% |
| Koch, et <i>al.,</i> 1993 ⁸⁸ | Furlong | 190 (2–5, mean 2.9) | ? | No revision or loosening |
| d'Antonio, et <i>al.</i> , 1992 ⁵⁴ | Omnifit | 320 (minimum 2) | mean 50 | No revisions |
| Capello, 1994 ⁸⁹ | Omnifit stem only | 5 (5) | mean 50 | Revision rate (pain/aseptic loosening) 3.3% |
| Geesink & Hoefnagels, 1995 ⁹⁰ | Omnifit | 100/118 (5.6–7.6) (3 | mean 53 I < 50 years) | 100% stem survivorship, 99% cup |

at 9 years, and the second⁹⁴ recorded relatively poor clinical and survival results for the RM stem in small numbers of patients followed-up for 7–9 years).

Other studies of uncoated press-fit cups, mostly with peg or screw-enhanced fixation, show generally poor results (see press-fit data table in the appendix). The one exception is that by Kennedy⁹⁵ who, in a C-rated study (ages not specified), reported good results at 3–6 years' follow-up for the Arthropor cup; however, this success is attributed to the exact reaming surgical technique used, rather than to the prosthesis design. In studies of the Ring prosthesis, adequate numbers of patients are followed-up but their ages are not reported.

In general, early clinical and survival results for the press-fit stems are not encouraging in comparison to either uncemented coated or cemented models. Results for threaded cups have generally been poor, and the design has been largely abandoned (a selection of observational study results are given in the data tables in the appendix).

Hybrid designs

In this category only one study, by Helfen and colleagues,⁹⁶ follows-up more than 200 hips and presents survival results. The maximum follow-up period in published studies is about 7–8 years. The study by Helfen and colleagues is summarised in *Table 22*, together with two other studies with the longest follow-up periods. Helfen and colleagues' study suggests good early clinical and survival results in patients who are probably somewhat younger than average for THR. Given wide confidence intervals, this type of design can be regarded as comparable with the best cemented designs for early survival results.

| Study | Prosthesis type | Number of hips (follow-up period, years) | Age (years) | Results |
|---|--|---|----------------|--|
| Helfen, et al., 1993 ⁹⁶ | Marburg | 212 (3–6) | mean 60 | n = 1, revision for loosening |
| Schmalzried & Harris, 1993 ⁹⁷ | Two stem- collared, screw-fix cup models | 97 (mean 6.5) | mean 61 | n = 1, revision for stem loose (in a custom component); n = 1, cup revision |
| Mohler, et al., 1995 ⁹⁸ | Harris-Galante | 120 (mean 5.2) | mean 67 | No revisions |

TABLE 22 Selected studies of hybrid prostheses

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Chapter 10

Summary of results in relation to key issues

The results included in this chapter are taken from RCTS and comparative studies only. First clinically important issues are considered:

• thigh pain, fracture, dislocation and bearing surface materials.

Then studies of factors that affect the performance of prostheses are considered, together with potentially confounding factors in the interpretation of study results:

• hospitals/surgeons, and patient ages and body mass.

Finally, studies are considered that report aspects of surgical (cementation) technique, fixation and one unusual prosthetic design.

Thigh pain

While thigh pain has been identified as a problem in users of uncemented coated femoral components, it is reported on less frequently as an separate outcome from general hip scale scores in observational studies of Charnley and other cemented stems. However, it is possible to comment on this issue on the basis of the comparative studies and trials reviewed here.

In summary, each of the five studies in which the thigh pain associated with porous-coated stems is compared with either cemented,^{42,43} press-fit⁹⁹ or hybrid designs,^{57,100} shows a higher and clinically more significant incidence in porous-coated models. Thigh pain has also been found to be significantly higher in uncoated press-fit compared with Charnley cemented prostheses.³⁷ The one study in which different porous-coated models are compared shows fairly consistent levels of thigh pain (range 17–21%) between them.⁶⁰

Fracture

In the following study, the effects of fractures on clinical outcome were investigated by comparing uncemented hips with different types of fracture (according to the position of the fracture on the femoral shaft) with similar prostheses which had not fractured.

Mallory and colleagues, 1989¹⁰¹

Within a 4-year period, 56 femoral fractures occurred in various types of cementless total hip arthroplasties. These were divided into three groups by the authors: Type I (80%), Type II (16%) and Type III (4%). A total of 96% of the fractures occurred intra-operatively and 4% from postoperative trauma. The average age of the patients was 50.4 years (range 21-81 years) and 55% were female; 61% of THRs were primary replacements, the remaining 39% being revisions (91% of these for loosening). The control group comprised randomly selected patients with cementless THRs without intraoperative fractures, whose prostheses were implanted during the same period. There were no statistically significant variations between the groups. Types I and II were compared to the controls for "improvement by operation" and their modified d'Aubigne-Harris scores. No statistical differences were found. C-rated.

Comments

The authors concluded that long-term problems were not associated with Type I fractures (proximal zone) and possibly not with Type II (middle zone), although the numbers in the study were too small to be sure. The number of Type III fractures (distal zone) (n = 2) was too small to draw any conclusions. This subject requires further investigation to determine more precisely the prognosis for such fractures.

Dislocation

The reasons for dislocations occurring in some hips were investigated in two studies which considered the same problem but from different angles: in one the effect of patient variables was assessed while in the other CT scans were used to assess the prosthesis components.

Hedlundh and Fredin, 1995¹⁰²

The median age in this group of patients was 70 years (range 22–94 years), approximately 68% were female and approximately 48% had osteoarthritis and 23% rheumatoid arthritis.

Out of 1838 patients who had received a Charnley prosthesis, 60 hips had dislocated; these were matched with 120 non-dislocated hips, which formed the control group. Mortality was higher in the patients in the dislocated group (53%) compared with those in the control group (24.5%, p < 0.001), although the median age at death was similar. In a logistic regression none of the tested factors proved to be related to dislocation; however, alcohol abuse in men was more common in the dislocation group (50%) than in the control group (18%) (p = 0.01). **C-rated.**

Pierchon and colleagues, 1994¹⁰³

Within a 2-year period, 38 patients with dislocations were treated; 53% were women, the average age was 57 years and 66% had a diagnosis of osteoarthritis. Müller prostheses were used in most cases (29 self-locking femoral types, five dysplasia types; 12 cups were cemented and 26 uncemented). Of the 38 patients, 11 had been operated on by the same surgeon on the contralateral side and had not dislocated; details of three further prostheses were added to these to form a control group (further details of types of prosthesis or patients details were not given). Component alignment analysis was by CT scan. No differences in mean cup abduction, cup anteversion or femoral neck anteversion was found. In seven of the dislocated hips which underwent re-operation, the possible reasons for dislocation, as diagnosed by CT scan, were only confirmed in two cases. In the other five cases, instability of the hip was caused by lack of tension in the soft tissues. C-rated.

Comments

Hedlundh and colleagues¹⁰² reported an increased mortality rate among those with a dislocation but this was thought to be caused by lack of muscular strength and decreased coordination rather than by old age. Pierchon and colleagues¹⁰³ also thought that dislocation was caused by lack of tension in the soft tissues. One interesting observation was the association between dislocation rates and alcoholic abuse in men.

Bearing surface materials

Some comparative studies have addressed this aspect of hip replacement results. Those reviewed here were given a low rating in the appraisal. The wear of different materials is implicated in the production of particulate debris which, in turn, is associated with osteolysis and loosening of the prosthesis. The results for different bearing surface combinations are commented on below.

Ceramic on ceramic

Only one study,⁵¹ which was C-rated, considered ceramic on ceramic bearing surfaces. The study compared cemented cups to uncemented screw cups in ceramic prostheses. Over a follow-up period of 1–12 years, 9% of all the prostheses required revision. No comments or analysis of the bearing surfaces are made in this study. This is a rare form of design.

Ceramic on polyethylene

Prostheses with metal femoral heads and polyethylene cups were compared with those with ceramic femoral heads and similar cups in two, C-rated studies. In both studies the ceramic-polyethylene combination gave superior results to the metalpolyethylene combination. In Müller-type prostheses,⁴⁰ 95% of the ceramic head hips had a wear rate of less than 0.2 mm/year compared with only 64-77% of the metal version (range of follow-up period, 2.5-9 years). A mean wear value of 0.26 mm was found in Weber-type prostheses with a ceramic rotating head over a mean follow-up period of 10 years;⁴¹ this was less than the mean wear found in the same type of prosthesis but with a metal rotating head (0.96 mm; p < 0.001). However, this last result should be viewed with caution as the two prostheses were implanted in different hospital settings.

Metal on polyethylene

The main metal used for femoral heads now is stainless steel, superseding the titanium alloy and cobalt-chrome alloy to which many published studies refer. It is difficult to comment on the metals used as a bearing surface because of many other factors being present in the published studies. For example, in one C-rated study,58 a cobalt-chrome BIAS stem (with an uncemented metal-backed cup) was compared with three titanium BIAS stems with different cups. The titanium stem with cemented polyethylene cup gave the best results, with the least amount of wear and no osteolysis, but a titanium stem with an uncemented metal-backed cup gave the worst results. It would have been useful to compare the results with a cobalt-chrome stem with polyethylene cup but this was not included in the study.

However, some general comments can be made. There appears to be less wear in those prostheses with a complete polyethylene cup compared with those with a polyethylene liner. Linear wear rates for the all-polyethylene cups tend to be about 0.05– 0.1 mm/year.^{41,58,104,105} Details of polyethylene-liner wear related to porous-coated prostheses were given in two further studies: both the mean wear (0.73 mm)¹⁰⁶ and wear rates (0.6–0.8 mm/year)⁶⁰ were higher than the results above and so may need to be considered when choosing this type of prosthesis.

Comments

Further analysis needs to be performed in order to gain a better understanding of the optimal materials for bearing surfaces, as wear and debrismediated osteolysis are considered to be important reasons for loss of fixation and subsequent failure.

Inter-surgeon and inter-hospital comparisons

In multi-surgeon and multicentre studies confounding effects might be introduced by systematic differences between surgeons and/or between hospitals (for example, in stocking some prosthesis designs but not others). A number of the RCTs and comparative studies illustrate these points.

Surgeons

Marston and colleagues, 1996¹⁰⁷

Surgeons in training performed 15/16 primary procedures, which subsequently required revision, using (in 14/16 cases) the anterolateral approach. (Difference in revision rates between experienced and trainee surgeons, p = 0.005; relative risk of requiring revision at 5–10 years postoperatively, 11.47 times greater for trainees, 95% confidence interval 1.53–86.06). Surgeons in training only performed the operation unsupervised after being considered fully competent by the consultants who had taught the technique. Technical errors were identifiable in 11 cases. No significant difference was found between the Stanmore and Charnley prostheses. **C-rated.**

Ahnfelt and colleagues, 199014

Information was available on 37 surgeons (mainly working in two hospitals), all of whom were categorised as experienced surgeons. Two of 33 surgeons had fewer complications of aseptic loosening than the others and one had more (p < 0.001) re-operations than any of the others. However, if complications were analysed taking into account the number of primary operations performed per year, there were no statistical differences. **C-rated.**

Hoffman and colleagues, 1994³³

Nine different prostheses of various types with different lengths of follow-up, implanted by six surgeons, were studied in multi-variable regression analysis. Prosthesis type was not significant. The surgeon performing the operation was a significant factor, particularly if the prosthesis used was standardised to the Charnley (p < 0.001). However, the results of a single surgeon were not as satisfactory as the overall results and this factor masked any difference attributable to prosthesis in the two main groups (Charnley, Müller). Unsupervised registrars performed no worse than other grades of staff. **C-rated**.

Hospitals

Ahnfelt and colleagues, 1990¹⁴

Rates of revision for aseptic loosening and deep infection were compared between different types of hospitals. Statistical differences were found between university (tertiary), regional (secondary) and community (primary) hospitals. University hospitals reported more infection than the others. This could be caused by the selection of patients with special problems, which demanded lengthy and extensive procedures.

In a comparison of aseptic loosening in all prostheses (except the Christiansen prosthesis and the surfacing replacements), regional hospital results were better than the others (p < 0.001). **C-rated.**

Hoffman and colleagues, 1994³³

Nine different prostheses were used by six surgeons at either a publicly funded hospital or a private clinic. Prostheses implanted in the private hospital survived only 70% as long as those performed in the public hospital (p < 0.001). The two patient groups were of a similar age, sex and natural life-expectancy. Average period of attendance at follow-up clinics was shorter in the private group than in the public group and may be a contributing factor but the multi-variable analysis was unable to explain the difference in survival of prostheses between these types of hospital. **C-rated.**

Schuller and Marti, 199041

The use of the same type of prosthesis was compared in a teaching hospital environment (with a metal head) and in a private clinic (with a ceramic head). The amount of wear measured differed significantly (p < 0.001) but the possible confounding effect of differences attributable to the hospital setting was not addressed – patient groups were considered clinically comparable although the "main differences between the groups were socio-economic". **C-rated.**

Comments

The evidence from these studies for the comparative effect of grade/experience of surgical staff upon prosthesis longevity is conflicting. Multivariable analysis of variance was not possible in the study by Ahnfelt and colleagues,¹⁴ so the respective contribution of surgeon, hospital and patientrelated factors could not be estimated. This study suggests that the more specialised centres have better results overall, measured in terms of aseptic loosening and revision.

Body mass

It is rare that studies such as the following A-rated study are performed even though patient variables are important to outcomes of THR. Patient characteristics should be researched more fully in hip prosthesis survival studies.

Lehman and colleagues, 1994²⁷

In this retrospective study, primary THRs without cement, implanted over a 7-year period, were divided into two groups dependent on the body-mass index of the patient concerned. Normal weight patients had an index of between 20 and 30 (n = 142 hips), while obese patients had an index of > 30 (n = 60 hips). The obese group had a subsection within it of those who were morbidly obese - body mass index of 40 or more (n = 8 hips). Those with a body-mass index of less than 20 were excluded. The patients, 30% of whom were female, had an approximate average age of 50 years, and 62% had a diagnosis of osteoarthritis. Normal weight and non-morbidly obese groups had a significant increase in each functional measure between prostheses- and postoperative evaluations (p < 0.001). The morbidly obese group also had increases, although smaller, in most of the measures (p = 0.01 - 0.05). In the normal weight group, 7% of cups and 7.7% of stems were either loose or revised, compared with 8% of cups and 1.7% of stems in the non-morbidly obese group (*p*, not significant). The morbidly obese group had no loose components and none required revision. A-rated.

Comments

This authors of this study concluded that obese patients (those with a body-mass index of > 30) could benefit from primary total hip arthroplasties without cement and that obesity did not markedly increase the operative risk. However, they do point out that "substantial differences might occur with long-term follow-up". This needs to be researched more fully.

Age groups

Neumann and colleagues, 1996¹⁰⁸

One surgeon performed 240 Charnley hip arthroplasties in 211 patients in just over 6 years and data on the patients were collected prospectively. A total of 52 hips were implanted in patients aged between 34 and 55 years, 37 (71%) of whom were available for follow-up after approximately 17 years. Of patients aged over 55 years, 41% were also available for follow-up after a similar period (n = 77/188). A diagnosis of osteoarthritis was made in 79% of cases. The only difference seen in Charnley Hip Scores was in the Function section, where the older group had slightly reduced scores. This was thought to be caused by a deterioration in general health. The number of revisions and loose components were higher in the younger group but this was not statistically significant. Thus the probability of survival at 20 years did not differ between the two groups (younger group = 88.3%, older group = 89.3%). **B-rated.**

Comments

There is conflicting evidence on the performance of different prostheses in different age groups. Age is used as a proxy for physical activity levels but this is not a straightforward assumption. The study above concluded that Charnley low friction arthroplasties can be used for younger patients with "excellent long-term results" comparable to those in an elderly age group. However, in the C-rated study by Hoffman and colleagues,33 in which various types of prostheses were assessed, the hips were reported to survive longer when implanted into older patients. Hips in patients over the age of 66 survived longer than those in younger patients (p < 0.05). More studies such as that by Neumann and colleagues¹⁰⁸ are needed, in which one type of prosthesis is compared in different age but otherwise matched groups, in preference to studies involving many types of THR from which only generalised conclusions can be drawn.

Cement types

The following paper investigated a new bone cement (Boneloc®) which had been developed to reduce both the leakage of chemicals and the curing temperature, both considered to be possible reasons for the failure of cemented prostheses. The new cement was compared to a conventional polymethyl methacrylate cement (Palacos[®]). The mechanical and chemical properties of Boneloc were assessed during laboratory tests and presented with the clinical results. The study reported the new Boneloc to have "inferior fixation" to the conventional Palacos, giving indications of increased risk of loosening. The authors suggest that this was probably caused by its mechanical properties and possibly by other mechanisms such as an increased release of monomers.

Thanner and colleagues, 1995¹⁰⁹

This was a comparison of two types of cement -Boneloc and Palacos - involving 30 hips in 30 patients, aged 63-76 years, 27 of whom had primary osteoarthritis. Full radiostereometric analysis was possible in 24 patients only at 1 year (one Boneloc patient had died). Palacos fixed cups had "a small" lateral migration while cups with Boneloc migrated medially (p = 0.03) and proximally (p = 0.04); 1/16 Palacos stems subsided 0.27 mm while 6/13 Boneloc stems subsided 0.22–1.0 mm (p = 0.005). Increased acetabular radiolucent lines and femoral "relative cement- cortical bone contact" occurred in the Boneloc group compared with Palacos (p = 0.04 and p = 0.03, respectively). Harris Hip and Pain Scores and a Visual Analogue Scale for pain improved postoperatively (p = 0.0004 - 0.002) but did not differ between the groups (*p*, not significant). **C-rated.**

Cementing techniques

Cementing techniques in Charnley prostheses have been assessed most frequently, as in the first two papers summarised below. In the third paper cementing techniques are not compared (the authors state that they did not differ greatly between the two groups) but differences between Charnley designs are assessed over the same period; thus, the results may impinge on the other studies.

Cornell and Ranawat, 1986¹¹⁰

Early cementing techniques were used to implant four different prostheses in 62 hips between 1971 and 1978 and modern cementing techniques were used in 16 hips (two types of prosthesis, 1979–80). The hips were followed-up retrospectively after 5 years. The patients had a mean age of 48 years, 79% having a diagnosis of osteoarthritis, and 55% were women. There was a lower incidence of radiolucent lines around the cups plus lower radiolucent scores in the modern technique group (p < 0.025for both). There were no revisions in either group. The modern technique group had no loose components by 5 years. By 10 years the early technique group had three cups loose. **C-rated**.

Ranawat and colleagues, 1988¹¹¹

One surgeon performed 155 operations using cemented prostheses and, from these, 100 were matched for age, sex, diagnosis and body weight. Between 1970 and 1975, 50 operations were performed using early cementing techniques; the rest were implanted after 1979 using modified techniques. After a 5-year follow-up, 8% of the early group had migrated compared with none of the modified group (p = ?) and the cumulative radio-

lucent score was found to be lower in the modified group (p = 0.0005). Within the 5 years no early technique hips were found to be loose or require revision. None of the cups in the modified technique group were loose or revised but one stem required revision because of loosening. **B-rated.**

Dall and colleagues, 1993¹¹²

Between 1970 and 1986 a variety of surgeons implanted 1309 Charnley low friction arthroplasties in 1809 patients. From this group 666 hips were assessed after approximately 8 years: 264 early generation design (1970–77) and 402 second generation design (1975–86). Approximately 77% of the patients had osteoarthritis, their approximate mean age was 60 years and 60% were women. The probability of survival with respect to loosening at 10 years was reported to be 99.35% for the early hips and 86.8% for the second generation hips (p < 0.0001). The revision rates for both were similar: 8% early, 9% second generation. **C-rated.**

Other studies

Other prostheses have also been assessed, as part of other studies, with respect to cementing techniques. Stanmore hips had a 10-year survival without revision probability of 91.6%, when first generation techniques were used, compared with 97.4% for second generation (p = 0.005).³² In another study, 307 T-28 and 162 TR-28 hips were implanted using early techniques and 99 MOSC hips were inserted using modern techniques. An increased incidence of femoral subsidence of > 5 mm in the T-28 and TR-28 hips compared with the MOSC hips (p, 0.004–0.0075) was attributed by the authors to the different methods of fixation.

Comments

The two studies which assessed cementing techniques in Charnley both showed lower radiolucent line scores and incidence to be associated with the modern cementing techniques. Over the 5-year follow-up period in both studies, this did not translate into higher revision or loosening rates but this may occur later. However, the second generation Charnley design hips in the third paper had a lower probability of survival, compared to the first generation and, if these hips were used together with the modern cementing techniques, the longer-term results might not be so clear.

Aseptic loosening

The study below was designed to assess the possible reasons for loosening within the Stanmore cemented prosthesis.

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Kristiansen and Steen Jensen, 1985¹¹³

A total of 33 Stanmore hips with aseptic loosening were compared with a matched control series without loosening. The diagnosis for 94% of the patients was osteoarthritis, their mean age was 64 years and the study had a mean follow-up period of 36 months. Previous operations had been undertaken in four of the revision group compared with none in the control group (p < 0.05). Loosening occurred more often when calcar bone stock was thin prior to surgery (p < 0.001); insufficient packing was found in 88% of the loose hips and 39% of the stable hips. A varus position of the stem was associated with loosening as opposed to the neutral or valgus positions. **B-rated.**

Comment

The factors associated with failure possibly contributed to the loosening of prostheses. There is scope for review of further good quality studies on the mechanics of loosening in other patients and in other types of prostheses.

Wire versus cable

One study compared these methods of fixation.

Kelley and Johnstone, 1992²⁶

Either a Charnley or an IOWA stem was paired with either a Charnley (22 mm) cup, an all-polyethylene (28 mm) cup or a metal-backed (22 mm) cup. Two methods of fixation were used: stainless steel wire (n = 162) or cobalt-chrome cable (n = 160); follow-up period was approximately 6 years. The patients' approximate mean age was 66 years, 52% were women and 81% had a diagnosis of osteoarthritis. Trochanteric union rates were 75% for the wired hips and 79% for those with cable. Breakage of the entire trochanteric fixation construction (all three wires or cables) occurred in 43% wire and 12% cable (the cables in 56% of the hips unravelled, 47% of these had no broken cables). Analysis of roentgenographs (performed independently of the surgeon and blinded where possible) showed loosening of the cup in 12% of wired hips and 23% of the cabled ones. The difference in cup loosening, adjusted for cup type, was significant (p = 0.003). A-rated.

Comments

Cable was introduced to improve trochanteric union rates but this study did not show any

significant results in this area. Bone destruction occurred more frequently with cable (p < 0.001) and was associated with debris coming from the cables themselves. Debris may be responsible for the higher incidence of cup loosening in those hips with cable. These results suggest that there is no advantage of cable over wire and, as the authors point out, caution should be used when considering the use of cable for trochanteric fixation.

Isoelastic hip versus porouscoated prosthesis

This paper was not included with other prosthesis comparisons because the Butel prosthesis is of a different type to all the others.

Jacobsson and colleagues, 1994¹¹⁴

Two senior surgeons operated on 56 patients (24 women, 32 men, mean age 52 years), of whom 75% had osteoarthritis; the rest had a variety of reasons for the unilateral hip operation. Patients were matched in pairs for sex, age, weight and radiographic appearance before being randomly selected (no details of method) to have a Butel (stem made of four rods for flexibility) or a PCA (rigid) stem (three different press-fit cups were used). Each pair was operated on by the same surgeon and was followed-up for 3 years. The PCA stem gave better results, as assessed by Harris Hip Scores (mean 94.4 compared with 78.5 Butel, *p*-value not given) and the number of prostheses definitely or probably loose (PCA 18%, Butel 86%). Both groups required three hips to be revised because of loosening (one further Butel hip was revised for other reasons). C-rated.

Comment

The Butel was "designed to obtain flexibility similar to the proximal femur by using four rods (titanium alloy) connected proximally and distally" and was supposed to " exhibit fewer signs of stressshielding". However, the porous-coated prosthesis gave better Harris Hip scores and was far more stable than the Butel system. Although the numbers of revisions were similar in both groups during the 3-year follow-up period, the increased number of Butel hips which were definitely or probably loose may indicate that more of these prostheses would require revision in later years than the PCAs.

Chapter II Economic model

Introduction

The aim in this chapter is to estimate the costs of THR using an economic model. The focus is on the model developed to incorporate relevant characteristics and costs which enables comparisons to be made of different prostheses. Results are presented by applying this model using available data. The model can also be applied as new data become available on the survival of existing prostheses, on new prostheses, on changes in costs or local data. Thus the results give an assessment of the state-of-the-art now, and the model enables these findings to be revised as new data become available. The model itself is therefore an equally important product of the research as are the results themselves.

Methods

The obvious costs of a THR are those of primary replacement. However, the total expected costs are, in fact, greater than this and may include the costs of revision.

The concept of total expected costs is based on those costs expected to be incurred over a number of years. In the case of THR, total expected costs are the sum of the primary replacement costs and the expected costs of revision. These expected costs of revision are the actual cost of revision multiplied by the probability that a revision will be performed. Thus a combination of a low revision rate and a low revision cost will result in a low expected cost of revision; likewise, a high revision rate combined with a high revision cost will result in a high expected cost of revision. Given a population who have had primary THRs, a number of revisions will be required in each future year and associated costs will therefore be incurred in each future year. For comparability, these expected costs are converted into their value now (present value). This conversion is required because a given quantity of money has different values in different years in the future. The basic principle is that the present value of £1 in the future is less than the value of £1 now. The conventional method of converting costs into their present value is called discounting and is explained in more detail below.

By calculating the total expected costs of THRs, comparisons between different prostheses can be made. Assume a choice of two prostheses: Y needs no revisions over 20 years and X has, say, a 1% per annum revision rate. Prosthesis Y costs £1000 more than prosthesis X. A purchaser, making a decision based on expected costs only, would chose Y rather than X if the expected costs of revisions of prosthesis X over the next 20 years were more than £1000 (and vice versa). Thus for equivalent total expected costs of revisions of prosthesis S over 20 years, primary plus expected costs of revisions of prosthesis X over thesis X must equal primary costs of prosthesis Y.

Comparisons of different prostheses can thus be made if details of primary and revision costs and survival data are known for both. The method can also be used for making comparisons for which costs are known but survival data are not. For example, assume that there are no survival data for prosthesis A but the costs of a primary replacement are known, and both costs and survival data are known for prosthesis B. If the primary replacement costs of prosthesis A are greater than the total expected costs of prosthesis B, then it is inevitable that the total expected costs for prosthesis A will be greater than those for prosthesis B. Even if prosthesis B had a higher revision rate than prosthesis A, B would still be preferred if a decision was based on cost alone.

This model calculates expected costs over 20 years and assumes that the quality of life of recipients is equal however many revisions are undertaken. Obviously, in terms of benefits to individual patients, any prosthesis with a lower revision rate would be preferred, as patients would not need to undergo repeated surgery. If long-term quality-oflife data were available for various prostheses, it might be possible to undertake a cost–utility analysis to compare properly the costs and benefits of THR. These data are, however, not available. Care should therefore be taken to consider the dis-benefits of repeated revisions when making choices between prostheses.

Empirical data are not readily available on all the costs which contribute to the total cost of a THR or on survival rates. When there are empirical data, these often indicate wide variations. Hence,

using mean values may give misleading results for the expected costs of revisions and of the choice between prostheses for different orthopaedic surgeons. When the data on which the calculation depends are subject to a degree of uncertainty, it is vital to undertake a sensitivity analysis in which 'high' and 'low' estimates are stated for each component that is subject to some imprecision. These high and low estimates are substituted in place of the original values and the effects on the final outcome examined. The input factors that have the greatest effect on the level of total expected costs can then be investigated to see if they would change the relative total expected costs.

The model

Previous articles based on similar methods have been published by Daellenbach and colleagues in 1990²³ and by Gillespie and colleagues in 1995.¹¹⁵ Daellenbach and colleagues developed a mathematical model based on costs and patient survival for comparative economic appraisal of cemented and cementless prostheses. Their results suggested the numbers of additional years a cementless prosthesis needed to last, above that of a cemented prosthesis, to justify its extra cost of NZ\$1200. The figures were given for a range of additional costs of revision.

Gillespie and colleagues¹¹⁵ used Swedish and Australian data to estimate the potential costeffectiveness of new prostheses with unknown outcomes for different age groups and mortality rates. The present value of the future costs of a prosthesis of known cost and survivorship was compared to the theoretical present value of a new prosthesis with known cost but unknown outcome. Their results indicate that possible future savings resulting from increased survival and lower revision costs do not justify the use of prostheses which cost substantially more than a conventional component.

Similarly, in 1996, Pynsent and colleagues¹¹⁶ suggested a model for purchasers based on a "lifetime care package". For a given initial outlay, a purchaser would buy a primary replacement and any subsequent THR revisions. The initial cost would take into account, among other factors, the quality of prosthesis in terms of expected revision rate. This computer-based model takes account of prosthesis failure, death of the recipient and rerevision rate. Its conclusion is that if this method of pricing lifetime care according to quality of prosthesis was adopted, then monitoring, and thus the availability of survival data, would improve. Additionally, there would be a disincentive to suppliers to publish overoptimistic survival rates.

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This is because the supplier charges a fixed cost for the care package and would thus incur a loss if the actual cost of lifetime care was higher than that advertised.

The model developed here is based on the equation given by Gillespie and colleagues¹¹⁵ and is used to estimate the present value of expected total costs of THR over 20 years.

The equation is of the form:

$$PVc_{j} = C_{j} + H + \sum_{i=0}^{19} \{ \underline{Lmi. \ Pc_{j}mi. \ (C_{j} + H + R)} \}$$
(1 + r)ⁱ

where

| where. | |
|----------------------------|--|
| C _j = | cost of prosthesis j |
| H = | hospital costs including separate |
| | categories for: |
| | – theatre costs |
| | – ward costs |
| | – prophylaxis costs |
| | physiotherapy costs |
| L <i>mi</i> = | probability of an individual at age m |
| | when receiving a hip replacement |
| | being alive in year <i>i</i> |
| P <i>c_imi</i> = | probability of prosthesis C _i in an |
| 5 | individual aged m needing to be |
| | revised in year <i>i</i> |
| R = | additional costs of a revision (i.e. |
| | |

additional hospital costs) $1/(1+r)^i =$ a discount factor where *r* is the discount rate, *i* = 0–19 where 0 is the year of the primary operation.

Essentially this gives the present value of prosthesis C as dependent upon initial prosthesis and hospital costs, plus the sum of expected future costs of revision. Future costs of revision are themselves dependent on the age of the recipient and the survival of the implant. All future costs are discounted.

Primary operation costs

Data on resource use were obtained from two collaborating hospitals in different regions of England. Both hospitals gave details of the prices they charged for primary unilateral THRs. These costs were broken down into theatre, ward, physiotherapy and prophylaxis costs for each hospital. One hospital also gave costs of revision surgery. Prosthesis costs were given separately.

For both hospitals, the cost per hour in theatre and the time spent in theatre was determined. One hospital had supplied these details in their prices. The other gave total theatre costs only, broken down into theatre medical staff and other theatre costs. From separate data on operation and anaesthetic time, average theatre time for primary replacements was estimated and thus the cost per hour of theatre time. Data were obtained for ward costs in a similar way. Both hospitals gave total ward costs for primary replacement. One hospital gave details of cost per day and the average length of stay; for the other ward, cost per day was estimated from data on the average number of days stay and the total ward costs supplied.

By sensitivity analyses it was possible to determine the effect on the present value of total expected costs of long and short theatre times and lengths of stay.

In three studies, by Francis and colleagues,¹¹⁷ Wittmann and colleagues,118 and Sharrock and colleagues,¹¹⁹ it is suggested that cementless prostheses reduce the risk of postoperative thromboembolic disease, while Laupacis and colleagues¹²⁰ found no difference in the frequency of deep vein thrombosis between two patient groups (cemented and cementless). Lieberman and Geerts¹²¹ suggest that prophylaxis against deep vein thrombosis reduces both symptomatic thromboembolism complications and saves lives, and saves subsequent healthcare expenditure. Data on prophylaxis costs provided by one of the collaborating hospitals indicated that they were a small proportion (1.8%)of total primary replacement costs. In summary, prophylaxis costs make up only a small proportion of total costs and the evidence suggests that prophylaxis against postoperative thromboembolic disease is cost-effective.

Prophylaxis and physiotherapy costs were supplied by one of the collaborating hospitals (Hospital A). The second hospital was not able to separate these costs from other costs and therefore those for Hospital A were used as a proxy and subtracted from theatre and ward costs as appropriate. To allow cost per hour in theatre and on the ward to be calculated (see above), prophylaxis and physiotherapy costs were included in the model independently from overall ward and theatre costs.

Data supplied by one of the hospitals suggested that prices charged for a revision are 1.19 times the price of a primary unilateral replacement; that is, the additional costs of revision are 19% greater than the primary replacement costs. Using this percentage, the additional costs of revision were therefore made proportional to the primary replacement costs for both hospitals. The additional costs for revision are due, in part, to the longer operation time (on average, 40 minutes extra) and longer length of stay (approximately 3 days). The model assumes that the impact of these extra times remains proportional to the costs of primary revision. This allows the sensitivity analyses to impact on both primary and revision costs.

In 1996, Pynsent and colleagues¹¹⁶ suggested that the overall costs of revision surgery were twice that of a primary replacement because of the longer operation time and length of stay in hospital. No empirical evidence, however, was presented to justify this assumption. Revision surgery can be complicated and difficult to perform, with the personnel undertaking the revisions requiring higher skill levels. As such, revision costs cannot be assumed to be equal to primary replacement costs. This issue was examined in the sensitivity analysis by altering the revision costs to double the primary costs and determining the effect on the total expected costs.

The two collaborating hospitals gave their own prosthesis costs. Both supplied the price charged to purchasers for 'a hip prosthesis'. This was the average prosthesis price for all types of prostheses used in the hospitals and was not the specific price of a Charnley or other model. The survival data and prosthesis cost of the Charnley are used as the gold standard in the model for comparison with other prostheses. We decided to model the equation using the hospitals' prosthesis costs first and then using the price of a Charnley prosthesis as quoted by Murray and colleagues.⁹¹ The costs of other prostheses were also taken from this paper to allow comparisons to be made between different prostheses using costs that were provided for the same year. This paper reviewed all manufacturers and distributors in the UK and listed prostheses supplied by most major competitors with their market price. Where survival data were available for other (non-Charnley) prostheses, these were used with associated prices to estimate total expected costs. However, prices may vary from those stated, dependent upon quantity purchased and arrangements with purchasing organisations. Local prices should be used where known. The published prices were used to indicate a range of market prices for the sensitivity analysis.

Prosthesis survival data

The probability of an implant needing revision in year *i* was estimated from published sources. As mentioned above, the survival data and prosthesis cost of the Charnley are used in the model as the gold standard for comparison with other types of prostheses. The survival data for the Charnley for up to 20 years have been published in various articles.^{7,9,122} The data from these sources were collated and a best estimate of the probability of revision in each year over 20 years was calculated. Gaps in the data were filled assuming a straight line relationship between two known points. The average revision rate per year over 20 years for a Charnley prosthesis was about 1% (ranging from a low of 0.5% to a high of 3%).

To estimate the present value of expected total costs for a range of competing prostheses, the same exercise was undertaken for other types. As our review of evidence has shown, there are few data available on the survival rates of many prostheses. Often the survival rate was known at only one or two points in time, for example, after 4 or 5 years. For these prostheses, a straight line was fitted through the known point(s) and 100% survival (at time zero). This rate was then extrapolated over 20 years. Obviously, survival may not be linear, and rates of revision will increase as the number of years since replacement increases. Some implants show a dramatic rise in revision rate after about 5 years. Care should be taken when interpreting the results of prostheses with limited survival data. A rise in revision rate above the linear rate assumed in the model would result in increased expected costs.

Much of the published survival data are reports from 'centres of excellence' and may not therefore reflect common practice in the UK where revision rates may be higher. However, as long as data from centres of excellence are used consistently for all prosthesis types, the comparisons ought to be a reliable guide to the relative performance of different prostheses. What matters is relative cost. However, if the model is to be used at local level to inform purchasing decisions, it is important to model local survival rates in the equation. An increase in the probability of revision will result in an increase in the total expected costs.

The sensitivity analysis gives total expected costs for straight line revision rates over 20 years of 3% and 5% per year.

Discount factor

The conventional way of accounting for costs (and/or benefits) of a treatment occurring over a number of years is to put them on the same basis by discounting. The value of $\pounds 1$ in *i* years time is less than the value of $\pounds 1$ now, even after allowing for inflation. This is because costs incurred in the future are less important to us than costs now. To allow for this change in value over time, costs

incurred in the future are multiplied by a weighting factor (the discount factor) thus enabling the comparison of current and future costs as if they occurred at the same time. The discount factor is $1/(1 + r)^i$, where *r* is the discount rate and *i* the year in which the costs (or benefits) occur.

The total expected costs of a hip replacement include the original replacement and the costs of any subsequent revisions. Revisions may occur in any year and the costs occur at the same time. For those revisions taking place in 15 or 20 years time, the present value of these costs will be small because the denominator of the discount factor becomes larger (as *i* increases). The discount factor applied to a cost 20 years into the future is about 0.39; that is, the present value of a cost incurred 20 years hence is only about 40% of its nominal value. This model estimates the total expected costs over a maximum of 20 years; however, for the reasons described above, these costs will be small.

The discount rate in the original calculation was assumed to be 5%. This figure was varied in the sensitivity analysis to 0% and 6%.

Mortality data

The probability (Lmi) of a patient who received a primary hip replacement at age *m* being alive in year *i* was calculated from OPCS Mortality Statistics for 1992.¹²³ The probabilities for males and females were modelled separately in the equation. Median age at primary operation (70 years) was calculated from data supplied by one of the hospitals. Swedish data supplied by Malchau and colleagues¹²² supports this by giving mean age at primary replacement for men as 67.5 years and for women 68.2 years. An age of 70 years and the corresponding probability of being alive in year *i* was used in the calculations for both hospitals.

In the absence of any other data it is assumed that individuals who have had a hip replacement have a mortality rate equal to the general population for their age group. However, the true mortality rate for individuals with osteoarthritis and rheumatoid arthritis is different from the general population.¹²² Current research by the Somerset and Avon Survey of Health (Personal communication, 1996) suggests that people with a THR may have a lower lifeexpectancy than average. Accurate data on true mortality rates are not known. If these data were available and used in this model, and the mortality rates were higher than for the general population, then total expected costs would be lower than suggested because of the greater number of individuals dying before their prosthesis needed replacing. A youngest age of 20 years and an oldest of 80 years was used in the sensitivity analysis. For elderly patients, the discount factor combined with the high mortality rate results in very small expected costs in 20 years time. However, for young patients, the low mortality rate and the increasing THR revision rate over time mean that a high proportion of younger individuals will survive longer than their implants and, despite the discount factor, these costs are still important. Young patients will live for more than 20 years (that is, longer than the span of the model) and this must be considered when comparing the results.

Assumptions

A spreadsheet model is used to estimate the total expected costs of one prosthesis relative to another. The results from the model are intended to further current knowledge and to aid decision-making, not to prescribe policy. This model is based on a number of simplifying assumptions.

- As explained above, the model assumes prices quoted in a 1995 paper.⁹ These prices may have changed and prices of prostheses may also vary between purchasing institutions. Any increases in prosthesis price will obviously increase total expected costs. More importantly, any change in the relative prices of prostheses may change their relative cost-effectiveness.
- A further assumption is that prosthesis revision rates are linear when long-term survival data are not known. These estimates are based on trends for the years immediately following primary replacement. The assumption that the rate is linear throughout the 20 years of the model will underestimate longer-term revision rates and, thus, underestimate total expected costs.
- The model assumes that mortality rates of THR recipients are equal to those of the general population. This assumption is made because of the lack of data on actual mortality rates of THR recipients. If actual rates are higher than average, then the model will overestimate total expected costs, and this may change rankings of cost-effectiveness. This is because, if the mortality rate of THR patients increased, thus reducing length of life, there would be no change in the total expected costs of a low revision prosthesis whereas there would be a reduction in number of revisions and, hence, costs of a high revision rate prosthesis.
- No account is taken in the model of re-revisions. There is, inevitably, a cumulative effect in that a number of primary replacements will fail, be revised and fail again. Revision THRs have a greater chance of needing a further revision.¹¹⁶

This is not incorporated in the model which assumes a maximum of only one revision over the 20-year period. Including re-revisions would increase the total expected costs.

Results

This section includes:

- an estimate of total expected costs, based on survival data for the Charnley prosthesis and on actual hospital costs
- a comparison of the total expected costs of other prostheses
- a sensitivity analysis.

An estimate of total expected costs (based on survival data of the Charnley prosthesis and actual hospital costs)

The costs provided by both Hospitals A and B are presented in *Table 23.* Published yearly survival rates for the Charnley prosthesis and the estimated revision rates used in the equation are presented in *Table 24.*

| TABLE 23 | Primary unilateral replacement costs in Hospital A |
|-------------|--|
| and Hospita | ıl B |

| Type of cost | Hospital A (£) | Hospital B (£) |
|---|----------------|-----------------|
| Prosthesis | 629 | 700 |
| Theatre | 1197 | 946 |
| Ward | 1651ª | 2533 |
| Prophylaxis | 66 | NA ^b |
| Physiotherapy | 71 | NA |
| Total for primary unilateral | 3614 | 4179 |
| (Additional revision co | osts) (693) | (NA) |
| (Total costs of revision | n) (4307) | (NA) |
| ^a Ward costs in Hospital overheads and exclude ^b NA, not available. | | d indirect |

If the revision rates from *Table 24* and the costs from *Table 23* are used in the model, with the average age of primary implant (70 years) and a discount rate of 5%, the present value of expected revision costs for a selection of years will be those shown in *Table 25* (for each hospital and for men and women separately). The primary replacement costs are the hospital and prosthesis costs for the initial replacement.

| Year i | Published survival rate (%) | Estimated revision rates [*] |
|--------|--------------------------------|---------------------------------------|
| I | 99.1 | 0.009 |
| 2 | 98.4 | 0.007 |
| 4 | 97.0 | 0.007 |
| 5 | 95.9 | 0.011 |
| 6 | 95.0 | 0.009 |
| 8 | 93.6 | 0.007 |
| 10 | 89.7 | 0.03 |
| 13 | 92.0 | 0.005 |
| 14 | 79.0 | 0.005 |
| 15 | 87.3 | 0.005 |
| 18 | 81.0 | 0.025 |
| 20 | 86.8 | 0.018 |
| | | |

TABLE 24 Published yearly survival rates for the Charnleyprosthesis

^{*} To avoid negative revision rates, when survival rates rose over time, the rates were assumed to be a straight line between the years on either side.

In the Methods section above, a choice of two implants was assumed, one needing no revisions over 20 years and the other having about a 1% revision rate (as in the above model). A prosthesis with an expected 100% survival rate over 20 years has costs over 20 years equal to primary replacement costs. A purchaser making a decision based on expected costs only would not be prepared to pay substantially more over 20 years for one prosthesis rather than the other.

The costs of primary replacement and expected revision costs over a number of years for men and women are presented in *Table 25.* The expected costs of revision for women are slightly higher than for men because of the lower mortality rate for women; that is, fewer women die before needing a revision.

In Hospital A, for men, the difference between the cost of a primary replacement (\pounds 3614) and the expected total costs over 20 years is \pounds 297, the expected costs of revisions. For Hospital B the difference in costs is \pounds 344. The expected revision costs over 20 years for women are \pounds 371 and \pounds 431 for Hospitals A and B, respectively.

These figures imply that, for male patients in Hospital A, assuming equal hospital costs for different prostheses, a purchaser would not be prepared to pay more than £297 extra, compared with the cost of the current prosthesis, for a new type of prosthesis. Paying more than £297 extra (that is, £926 in total) for the 'no revisions' prosthesis would result in the costs over 20 years being greater than costs using the current implant. Using the costs supplied by Hospital B, the maximum extra a purchaser would be prepared to pay for a no revisions prosthesis is slightly higher at £344 (£973 in total).

TABLE 25 Present value of expected revision costs for males and females for a selection of years (average hospital prosthesis and Charnley prosthesis costs separately)

| | Present value of total expected costs (£) | | | | | | | | | |
|---|---|--------|--------------------------|--------|--------------|--------|--------------------------|--------|--|--|
| | Hospital A | | | | Hospital B | | | | | |
| Prosthesis price | 629ª 3614 | | 353 ^ь 3338 | | 700° 4179 | | 353 ^ь 3832 | | | |
| Primary replacement costs (including prosthesis) | | | | | | | | | | |
| Expected costs of revisions | Male | Female | Male | Female | Male | Female | Male | Female | | |
| At end of 5th year | 136 | 145 | 127 | 135 | 158 | 168 | 47 | 156 | | |
| At end of 10th year | 244 | 278 | 228 | 260 | 283 | 323 | 263 | 301 | | |
| At end of 15th year | 265 | 310 | 248 | 290 | 308 | 360 | 286 | 335 | | |
| At end of 20th year | 297 | 371 | 278 | 348 | 344 | 431 | 320 | 401 | | |

^a Average prosthesis cost in Hospital A, including cement (£71)

^b Cost of Charnley prosthesis⁹

^c Average prosthesis cost in Hospital B

Similar figures using the lower prosthesis prices quoted by Murray and colleagues⁹ give the maximum extra a purchaser would be prepared to pay for a no revisions prosthesis in men as £278 and £320 for Hospitals A and B, respectively (£631 and £673 in total, respectively). For women, the corresponding figures are £348 and £401, respectively (£701 and £754 in total, respectively).

Obviously, given a choice, the recipient of an implant would prefer the prosthesis with the lowest revision rate or not to have to undergo revision surgery at all. Here only the expected total costs of THR have been examined, without considering any benefits.

Comparison of the total expected costs of other prostheses

An indication is presented here of the total expected costs of a range of competing prostheses, for comparison with the above estimates which used the survival rates for the Charnley prosthesis. Published costs and estimates of survival rates were used in the model together with the cost data from Hospital A.

These results are based on published survival rates from centres of excellence which may not reflect common practice but do compare prostheses in similar settings. The expected costs of both prostheses will be greater in hospitals where the prosthesis survival rate is lower.

The results are given separately for prostheses where the longer-term survival rates are available (i.e. more than 10 years) and for prostheses where only short-term survival rates are known (i.e. less than 10 years).

Prostheses evaluated over the long term (with 10 years or more data on survival)

Survival rates of 10 years or more were used for five types of cemented prosthesis and one cementless prosthesis. These data are presented in *Table 26*, together with the price of the prosthesis, if available.

The results were derived separately for men and women, using the following assumptions:

- hospital cost data from Hospital A
- for cemented prostheses, the average cost (£629 including cement) from Hospital A was used if no prosthesis specific cost was available
- for cementless prostheses, the average price (£1150) of those listed by Murray and colleagues⁹ was used if no specific prosthesis cost was available
- a recipient aged 70 years at time of implant (unless otherwise stated)
- a discount rate of 5%
- the cost of reoperation remained proportional to the cost of primary operation (excluding prosthesis cost)
- linear prosthesis revision rates (except for the McKee-Farrar prosthesis for which the actual rates were known).

Actual revision rates will probably rise over time leading to greater expected costs than those indicated here. The resulting expected costs using these linear assumptions are presented in *Table 27.*

| Make/type | Price (£) | 5-year survival rate (%) | l 0-year survival rate (%) | l 5-year survival rate (%) | 20-year survival rate (%) |
|---|------------------|--------------------------------|----------------------------------|------------------------------------|---------------------------------|
| Cemented | | | | | |
| McKee-Farrar ⁷⁴ | - | 94.7 | 91.0 | 84.3 | 48.9 |
| Stanmore ⁹¹ | 285 (250–320) | _ | 94.0 | 91.0 | _ |
| Howse ⁷⁹ | - | _ | 90.0 | 80.0 | _ |
| Exeter | 340 | 98.0 ⁹ (4 years) | _ | 89.0 ⁷⁶ (13.4 years) | - |
| Cemented alumina-alumina (age \leq 50 years) ¹²⁴ | - | 95.0 | 94.7 | _ | _ |
| Cemented alumina-alumina (age > 50 years) ¹²⁴ | - | 95.0 | 80.4 | - | _ |
| Cementless | | | | | |
| AML ⁸² | 799 | - | 85.0 (12 years) | - | _ |

TABLE 26 Published prices of prostheses and their survival rates

| | | Expected total costs (£) | | | | | | | |
|---|-----------|--------------------------|---------|---------------|--------|---------------|--------|--|--|
| Make/type of | Assumed | Over I | 0 years | Over 15 years | | Over 20 years | | | |
| prostheses Charnley | price (£) | Male | Female | Male | Female | Male | Female | | |
| | 353 | 3566 | 3598 | 3586 | 3628 | 3616 | 3686 | | |
| Cemented | | | | | | | | | |
| Stanmore | 356 | 3489 | 3506 | 3514 | 3543 | 3522 | 3560 | | |
| Exeter | 411 | 3579 | 3604 | 3621 | 3667 | 3636 | 3697 | | |
| Cemented alumina-alumina $(age \le 50 \text{ years})^a$ | 629 | 3813 | 3814 | 3874 | 3875 | 3919 | 3922 | | |
| Howse | 629 | 3877 | 3907 | 3966 | 4040 | 3998 | 4102 | | |
| McKee-Farrar | 629 | 3855 | 3883 | 3909 | 3965 | 4023 | 4189 | | |
| Cemented alumina-alumina (age > 50 years) | 629 | 4061 | 4130 | 4149 | 4261 | 4179 | 4322 | | |
| Cementless | | | | | | | | | |
| AML | 799 | 4125 | 4165 | 4343 | 4470 | 4406 | 4610 | | |

TABLE 27 Expected total costs of Charnley prosthesis and seven comparison prostheses

TABLE 28 Published prices of prostheses and their survival rates

| Make/type | Price of prostheses (£) | 4-year survival rate (%) | 5-year survival rate (%) | 7-year survival rate (%) | 9-year survival rate (%) |
|----------------------|-------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| Cemented | | | | | |
| Müller straight stem | 334 | _ | 99.0 ⁹¹ | _ | 94.0 ⁹¹ |
| CAD | _ | _ | _ | 95.1 ¹²² | _ |
| Lubinus IP | _ | _ | _ | 95.5 ¹²² | _ |
| Spectron | 700 | 98.0 ⁹¹ | 97.9 ¹²² | _ | _ |
| Lubinus SP | 700 | 98.5 ¹²² | - | - | - |
| Cementless | | | | | |
| PCA | _ | _ | 94.4 ¹²² | 95.0 ¹²⁶ | _ |
| Omnifit | 1260 | _ | 99.0 | _ | _ |
| | | | (5.6 years) | | |
| Harris-Galante | _ | _ | 96.71 ¹²⁵ | - | _ |

The expected total costs of the Charnley are £3616 and £3686 per hip over 20 years for men and women, respectively. From *Table 27*, prostheses with survival data of 10 or more years, the Stanmore, with a prosthesis and cement price of £356, has expected total costs of £3522 (£3560 for women) over 20 years, almost £100 (£126) less than the Charnley. The Exeter prosthesis has similar costs over 20 years to the Charnley at £3636 (£3697), with an initial prosthesis and cement cost of £411. The one cementless prosthesis (DePuy's AML) at £799 is seemingly not a cost-effective option for either men or women given the assumptions used in this model.

Prostheses evaluated over the short term (with less than 10 years data on survival)

Survival rates of less than 10 years were used for six cemented and three cementless types of prosthesis. These data are presented in *Table 28*, together with the price of prosthesis if available. The results were derived from the model using the same assumptions as above. The resulting expected costs are given in *Table 29*.

| | | Expected total costs (£) | | | | | | | |
|----------------------|----------------------|--------------------------|--------|---------------|--------|---------------|--------|---------------|--------|
| | Assumed price (£) | Over 5 years | | Over 10 years | | Over 15 years | | Over 20 years | |
| | | Male | Female | Male | Female | Male | Female | Male | Female |
| Charnley | 353 | 3465 | 3473 | 3566 | 3598 | 3586 | 3628 | 3616 | 3686 |
| Cemented | | | | | | | | | |
| Müller straight stem | 405 | 3422 | 3424 | 3535 | 3561 | 3587 | 3639 | 3606 | 3676 |
| Lubinus IP | 629 | 3727 | 3733 | 3784 | 3802 | 3811 | 3842 | 3820 | 3861 |
| CAD | 629 | 3731 | 3738 | 3798 | 3819 | 3829 | 3866 | 3840 | 3887 |
| Lubinus SP | 771 | 3821 | 3825 | 3858 | 3870 | 3875 | 3895 | 3881 | 3907 |
| Spectron | 771 | 3831 | 3835 | 3877 | 3890 | 3896 | 3919 | 3903 | 3932 |
| Cementless | | | | | | | | | |
| Omnifit | 1260 | 4276 | 4278 | 4295 | 4302 | 4305 | 4315 | 4308 | 4321 |
| Harris-Galante | 1150 | 4259 | 4266 | 4329 | 4352 | 4362 | 4401 | 4374 | 4424 |
| PCA | 1150 | 4270 | 4278 | 4346 | 4370 | 4381 | 4423 | 4394 | 4447 |

TABLE 29 Expected total costs of Charnley and eight comparison prostheses

Some of the figures on which *Tables 27* and *29* are based use an assumed prosthesis price and estimates of revision rates that are probably lower than actual revision rates. The results should therefore be treated with some caution. However, *Tables 27* and *29* do allow comparison of costs over a number of years between the gold standard of the Charnley and the competing prostheses.

Table 29 presents the results for prostheses with less than 10 years survival data; actual survival rates over 20 years may be different from the linear ones assumed. Only the Müller straight stem at \pounds 3606 (\pounds 3676 for women) over 20 years, for an initial prosthesis and cement cost of \pounds 405, is similar in cost to the Charnley. All of the cementless prostheses have expected costs over 20 years of about \pounds 700 more than a Charnley prosthesis and all are more costly than any of the cemented prostheses.

Sensitivity analysis

The purpose of a sensitivity analysis, as described above, is to indicate how sensitive the results are to certain key components in the model. The most important consideration here is the effect that changes in the key assumptions will have on the expected costs of revisions and on the relative cost-effectiveness of different prostheses in terms of total expected costs. For simplicity, the sensitivity analyses presented here model the equation for men and for Hospital A's costs only. The sensitivity analyses explore three main issues.

- 1. What effect do changes in the different inputs to the model have on total expected costs?
- 2. Does the relative cost-effectiveness of different prostheses change as these inputs are changed?
- 3. In general, what are the relationships between prosthesis price and revision rate?

The effect of changes in the different inputs to the model on total expected costs

The purpose of this sensitivity analysis is to determine the effect on total expected costs over 20 years of different input data. For example, the model assumes that the length of stay as an inpatient after a THR is 13 days. This is the average length of stay from local data but other data suggest that the range may be from 9 days to 22 days. Clearly, substituting 22 days into the model for 13 days will raise costs. The question is – by how much over 20 years? Other data in the model are also subject to such uncertainties and, hence, are explored in this sensitivity analysis.

Using the Charnley prosthesis cost and survival data plus other assumptions as explained above, each of the main components in the model are altered, as appropriate, to a low and high estimate. Of the seven components in the model, three impact predominantly on costs in the current period, one affects future costs alone (revision costs), two affect the expectation of future costs (revision rate and recipient age) and one affects the weight given to future costs (the discount rate). The original data and the estimates used in the sensitivity analysis are presented in *Table 30.* The effects on the total expected costs over 20 years of varying the level of major current costs (that is, hospital and prosthesis costs) are shown in *Table 31.*

TABLE 30 Estimates used in the sensitivity analysis

| | High | Hospital A | Low |
|---|-----------------------------|-------------------|----------------------------|
| Prosthesis | £1321.00 ^a | £629.00 | £321.00 ^a |
| Theatre: length of stay | 246 minutes ^b | 144 minutes | 60 minutes ^b |
| Ward: length of stay | 22 days ^c | 13.2 days | 9 days ^c |
| Additional costs of revision | £3613.96 ¹¹⁶ | £693.00 | £0 |
| Age at operation | 40 years | 70 years | 80 years |
| Revision rate | 5% | (1%) ^d | _e |
| Discount rate | 0% | (5%) | 6% |
| ^a From Murray, et al., | 1995, ⁹¹ plus | £71 for cemer | nt |
| ^b Data from Hospital | A (Personal c | communication, | 1997) |
| ^c Data from Trent Reg 1997) | ion for 1990 | (Personal com | munication, |
| ^d Rates assumed in ou | ır basic mode | el | |
| ^e Zero revision rate: no | o extra costs | | |

 TABLE 31 Effects on total expected costs over 20 years of varying the level of major current costs

| | High cost (£) | Low cost (£) | Current cost differ- ence (£) (high – low estimate) | Total expected cost differ- ence (£) (high – low total costs) |
|----------------------------|---------------------|--------------------|---|--|
| Prosthesis | 4650 | 3581 | 1000 | 1069 |
| Theatre: length of stay | 4831 | 3153 | 1500 | 1677 |
| Ward: length of stay | 5160 | 3314 | 1560 | 1846 |

The effect of a change in prosthesis price from $\pounds 250$ to $\pounds 1250$ falls on both current and future costs. From *Table 31* it can be seen that an increase of $\pounds 1000$ in prosthesis price results in increased expected future costs of $\pounds 1069$ over 20 years. Obviously $\pounds 1000$ of this increase occurs in the current period; thus, the present value of expected future costs is only about $\pounds 70$ over 20 years.

The range of time spent in theatre is taken from data provided by Hospital A (1–4 hours). From an average time of 144 minutes and total theatre costs, the cost per hour of theatre time was calculated to be about ± 500 . Thus an increase in theatre time of 3 hours results in an increase in the cost of a primary operation of about ± 1500 . From *Table 31*, the increase in total expected costs over 20 years of a 3-hour increase in theatre time is ± 1677 . When these costs are compared with the increase in cost of the primary operation, it is clear that the additional future costs are relatively small (about ± 170).

The cost of an inpatient stay in Hospital A was calculated as about £120 per day. As above, the number of days stay as an inpatient may range from 9 days to 22 days (1990 data from Trent Region: Personal communication, 1997). Such an increase in stay (13 days) results in an increase in the cost of a primary operation of about £1560. The resulting increase in expected future costs over 20 years is £1846. Thus, it is clear that the expected future costs are about £285.

For each of the three analyses above, the impact on total expected costs is between £1000 and £2000. These are substantial increases for an operation that costs about £3500. Most of these costs are incurred in the current period and have very little impact on future expected costs.

The effects on total expected costs over 20 years of varying four factors affecting the level of expected future costs are shown in *Table 32:* discount rate, additional costs of revision, recipient age, and revision rate. The results are modelled using the assumptions for prostheses evaluated over the long term (page 51).

The discount rate affects all costs incurred; the further into the future the costs are incurred, the greater the effect (i.e. the smaller the present value of the discounted costs). Reducing the discount rate from 6% to 0% results in an increase in the current value of expected future costs of £143 when calculated over 20 years. The discount rate used in the model is 5%. The difference in costs between an assumed rate of 5% and 6% is very small (£14).

The effect of any **additional** costs of revision, that is, revision costs in excess of the costs of a primary replacement, occur, by definition, in the future. These costs are thus subject to the effects of rate of revision, survival of recipient and discount rate. Comparing an extra revision cost of £3614 to no extra cost of revision gives a small additional expected future cost of over 20 years of £249. This means that, despite the higher level of skill needed for revision surgery, the costs over 20 years are relatively low.

The probability of a recipient surviving to a time when a revision may be needed is dependent on age at operation. The increase in expected costs over 20 years for a primary replacement in a 40-year-old compared with an 80-year-old man is £378. This model incorporates a maximum of 20 years costs. Obviously, an individual aged 40 years could incur at least two 20-year periods; hence, the lifetime costs would be far greater. However, the further into the future that the costs are incurred, the lower their present value because of the discount factor (see page 48 above) and therefore the less 'important' they become.

It is clear from *Table 32* that the revision rate has the largest effect on the total expected costs over 20 years. A change in the revision rates of prostheses from the best estimate of Charnley prosthesis survival (approximately 1% revision per year) to 5% per year results in additional expected costs over 20 years of £1320. The costs over 20 years with a 3% revision rate would be £4584 (£673 more than a 1% revision rate (not shown)).

From *Tables 31* and *32* it is apparent that the factors affecting the total expected costs of THR by the greatest amounts are prosthesis and hospital costs and the revision rate.

 TABLE 32 Effects on total expected costs over 20 years of varying factors affecting future costs

| | High cost (£) | Low cost (£) | Total expected cost differ- ence (£) (high – low total costs) |
|--|---------------------|--------------------|--|
| Discount rate | 4036 | 3893 | 143 |
| Additional costs of revision | 4112 | 3863 | 249 |
| Recipient age | 4163 | 3785 | 378 |
| Revision rate | 5230 | 3911 ª | 1320 |
| ^a Using 1% per year revision ra | te | | |

Does the relative cost-effectiveness of different prostheses change as input costs are changed? Given that, for named prostheses, prices and revision rates are known, the variable input in the model that will have a large impact on total expected costs is hospital costs. In order to establish any changes in the relative costeffectiveness of different prostheses, low and high estimates of hospital costs (combined theatre and ward costs) are modelled – that is, 60 minutes in theatre and 9 days as an inpatient as the low cost estimate and 246 minutes and 22 days as the high cost estimate. The results are presented in *Table 33*.

From *Table 33*, it can be seen that there are very few changes in the relative cost-effectiveness of prostheses as hospital costs are changed. The prostheses listed in the table are ranked according to the low cost estimate. The McKee-Farrar and CAD prostheses are the only ones to change order in the ranking when the higher hospital costs are modelled. The McKee-Farrar prosthesis moves down the ranking by two places and CAD by one place.

| TABLE 33 | Relative cost-effectiveness of different prostheses |
|--------------|---|
| using low an | d high estimates of hospital costs |

| Make/type | Total expec | ted costs (£) |
|--|------------------------------|------------------------------|
| | Low estimate | High estimate |
| Charnley | 2262 | 5785 |
| Prostheses with 10 or mor | re years survi | val data |
| Cemented | | |
| Stanmore | 2205 | 5633 |
| Exeter | 2298 | 5781 |
| McKee-Farrar | 2327 | 6257 |
| Cemented alumina–alumina (age \leq 50 years) | 2500 | 5941 |
| Howse | 2613 | 6217 |
| Cemented alumina–alumina (age > 50 years) | 2729 | 6503 |
| Cementless | | |
| AML | 2944 | 6748 |
| Prostheses with less than | 10 years surv | vival data |
| Cemented | | |
| | | |
| Müller straight stem | 2277 | 5736 |
| Müller straight stem Lubinus IP | 2277 2498 | 5736 5938 |
| - | | |
| Lubinus IP | 2498 | 5938 |
| Lubinus IP CAD | 2498 2511 | 5938 5970 |
| Lubinus IP CAD Lubinus SP | 2498 2511 2590 | 5938 5970 5950 |
| Lubinus IP CAD Lubinus SP Spectron | 2498 2511 2590 | 5938 5970 5950 |
| Lubinus IP CAD Lubinus SP Spectron Cementless | 2498 2511 2590 2604 | 5938 5970 5950 5984 |

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The reason for the change in relative costeffectiveness of the McKee-Farrar is that the prosthesis survival rate falls quite markedly after about 15 years (15-year survival 84%, 20-year survival 49%). As more revisions are needed, the increased hospital costs impact to a greater extent on future costs than for the other prostheses with lower revision rates. The survival data for the McKee-Farrar prosthesis were available and have been used for each and every year up to 20 years. Such detailed data were not available for other prostheses and, hence, survival rates were assumed to be linear. It may be that the survival rates of other prostheses fall equally quickly as that of the McKee-Farrar, thus increasing the high cost estimate of other prostheses.

In the bottom half of *Table 33*, showing prostheses with less than 10-years' survival data, the CAD prosthesis moved down the ranking by one place to below the Lubinus SP when higher hospital costs were used. The assumed linear revision rates for the CAD and Lubinus SP prostheses are similar (0.007 and 0.004 per year, respectively). The reason for the Lubinus SP being more expensive using low hospital costs is that the prosthesis itself is more expensive than the assumed price of the CAD (£771 and £629, respectively, including cement). As hospital costs increase, prosthesis price becomes a smaller proportion of total costs and the higher revision rate of the CAD becomes the most influential factor on total expected costs.

Overall, the relative cost-effectiveness of different prostheses does not appear to be altered under assumptions of different hospital costs. The main finding is that if revision rates increase dramatically over time, increases in hospital costs will have a greater impact on total expected costs than lower revision rates.

The relationship between prosthesis price and revision rate

For general reference, the relationship in terms of expected total costs over 20 years between differently priced prostheses, revision rates and discount rates are shown in *Table 34.* Hospital costs in these scenarios are assumed to be the same for all prices of prosthesis. Prosthesis costs range from £400 to £2000, revision rates from zero to 5% per year, and the discount rate from zero to 6%.

Where the revision rate given in *Table 34* is zero, the total expected cost shown is the cost of primary operation only. This is not affected by changes in the discount rate as there are no future costs. The important question to be answered from this information is whether or not greater costs of prosthesis result in lower total expected costs because of lower expected revision rates.

Assuming an 'average' prosthesis price and revision rate of £700 and 2%, respectively, with a 5% discount rate, Table 34 gives the total expected costs as £4342 over 20 years. As expected, the higher the cost of prosthesis, the lower the revision rate must be to make the THR cost-effective in terms of total expected costs. For a £1000 prosthesis to be comparable in total expected costs with such a £700 prosthesis, revision rates must be 1% or less per year over the 20 years. A £1500 prosthesis costs over £100 more for just the primary operation so would be required to have a zero revision rate even to be considered in comparison to a $\pounds700/2\%$ revision rate prosthesis. Primary replacement costs for a £2000 prosthesis are equivalent to total expected costs over 20 years of a ± 700 prosthesis with a 4%revision rate.

The cementless prostheses listed in *Tables 27* and *29* and the more expensive prostheses in *Table 33* have greater total expected costs under the assumptions in this model than cemented/lower priced prostheses. Cementless prostheses are generally more expensive than cemented but may last longer in younger patients. If this is the case then, in younger patients, it could be expected than a £1500 prosthesis with a 0% or 1% revision rate may be more cost-effective than a £700 prosthesis with, say, a 2% revision rate. The relative cost-effectiveness of different prices of prosthesis and revision rates in a 40-year-old patient are presented in *Table 35*.

If the revision rate of a cemented prosthesis (price £700) in a 40-year-old patient is 3% per year over 20 years, the total expected costs would be £5314. Using this as the comparison figure, it is clear that more expensive prostheses can be more cost-effective with a lower revision rate. For example, assume a cementless prosthesis is priced at £1500. With a 1% revision rate, this prosthesis would be more cost-effective than our $\pounds700/3\%$ comparison (£5127 and £5314, respectively). Likewise, both a £1000/2% revision rate and £2000/no revisions prosthesis would be more cost-effective over 20 years (total expected costs £5146 and £4985, respectively).

The conclusions that can be drawn from *Tables 34* and *35,* under the assumptions made in this model, are that:

• for patients aged 70 years at primary THR, lower priced prostheses with 1–2% revision rates are

| Prosthesis cost (£) | Revision rate | Total expected costs (£) | | | | |
|------------------------|----------------------|--------------------------|--------------------|--------------------|--|--|
| | (% per year) | (0% discount rate) | (5% discount rate) | (6% discount rate) | | |
| 400 | 0 | _ | 3385 | _ | | |
| | I | 3803 | 3691 | 3675 | | |
| | 2 | 4220 | 3997 | 3965 | | |
| | 3 | 4638 | 4303 | 4255 | | |
| | 4 | 5055 | 4609 | 4545 | | |
| | 5 | 5473 | 4915 | 4834 | | |
| 700 | 0 | _ | 3685 | _ | | |
| | I | 4133 | 4014 | 3996 | | |
| | 2 | 4582 | 4342 | 4307 | | |
| | 3 | 5030 | 4671 | 4619 | | |
| | 4 | 5478 | 4999 | 4930 | | |
| | 5 | 5927 | 5328 | 5241 | | |
| 1000 | 0 | _ | 3985 | _ | | |
| | I | 4464 | 4336 | 4318 | | |
| | 2 | 4943 | 4687 | 4650 | | |
| | 3 | 5422 | 5038 | 4983 | | |
| | 4 | 5901 | 5390 | 5315 | | |
| | 5 | 6380 | 5741 | 5648 | | |
| 1500 | 0 | _ | 4485 | _ | | |
| | I | 5015 | 4874 | 4853 | | |
| | 2 | 5545 | 5262 | 5221 | | |
| | 3 | 6076 | 5651 | 5589 | | |
| | 4 | 6606 | 6040 | 5957 | | |
| | 5 | 7136 | 6428 | 6325 | | |
| 2000 | 0 | - | 4985 | - | | |
| | I | 5566 | 5411 | 5389 | | |
| | 2 | 6148 | 5837 | 5792 | | |
| | 3 | 6729 | 6264 | 6196 | | |
| | 4 | 7311 | 6690 | 6600 | | |
| | 5 | 7892 | 7116 | 7003 | | |

TABLE 34 Relative cost-effectiveness over 20 years for a range of prosthesis costs, revision rates and discount rates in a recipient aged 70 years

usually more cost-effective than higher priced prostheses even with lower revision rates

• for younger patients, aged 40 years at primary replacement, higher priced prostheses with low revision rates can be more cost-effective than less expensive ones with higher revision rates.

Summary and conclusions of the economic analysis

The model presented above estimates the relative cost-effectiveness of different prostheses in terms of total expected costs. The results are intended to assist decision-making, not to be a prescription for policy.

The model is dependent upon a number of simplifying assumptions because of limitations

in the data. These assumptions may affect both the total expected costs and the relative costeffectiveness of prostheses in the following ways.

Total expected costs would increase and relative cost-effectiveness may change if re-revisions were included in the model. For a prosthesis with a high revision rate, the cumulative effects of the costs of re-revision would be greater than for a prosthesis with a lower revision rate. For example, in *Tables 34* and *35*, high cost/low revision prostheses may become more cost-effective than low cost/higher revision rate prostheses.

Data on the survival of many of the prostheses are limited. Some survival data are only available for up to 4 or 5 years. The model assumes linear extrapolation of survival data to 20 years. The survival rate of many prostheses may in fact fall (sometimes

| Prosthesis cost (£) | Revision rate | Total expected costs (£) | | | | |
|------------------------|----------------------|--------------------------|--------------------|--------------------|--|--|
| | (% per year) | (0% discount rate) | (5% discount rate) | (6% discount rate) | | |
| 400 | 0 | _ | 3385 | _ | | |
| | I | 4171 | 3891 | 3853 | | |
| | 2 | 4957 | 4397 | 4322 | | |
| | 3 | 5744 | 4903 | 4790 | | |
| | 4 | 6530 | 5408 | 5259 | | |
| | 5 | 7316 | 5914 | 5727 | | |
| 700 | 0 | _ | 3685 | _ | | |
| | I | 4529 | 4228 | 4188 | | |
| | 2 | 5373 | 4771 | 4691 | | |
| | 3 | 6217 | 5314 | 5194 | | |
| | 4 | 7061 | 5857 | 5697 | | |
| | 5 | 7906 | 6400 | 6200 | | |
| 1000 | 0 | _ | 3985 | _ | | |
| | I | 4887 | 4565 | 45,228 | | |
| | 2 | 5789 | 5146 | 5060 | | |
| | 3 | 6691 | 5726 | 5597 | | |
| | 4 | 7592 | 6306 | 6135 | | |
| | 5 | 8494 | 6887 | 6672 | | |
| 1500 | 0 | _ | 4485 | - | | |
| | I | 5483 | 5127 | 5080 | | |
| | 2 | 6481 | 5770 | 5675 | | |
| | 3 | 7480 | 6412 | 6269 | | |
| | 4 | 8478 | 7054 | 6864 | | |
| | 5 | 9476 | 7697 | 7459 | | |
| 2000 | 0 | _ | 4985 | _ | | |
| | I | 6080 | 5689 | 5637 | | |
| | 2 | 7174 | 6394 | 6289 | | |
| | 3 | 8269 | 7098 | 6942 | | |
| | 4 | 9364 | 7802 | 7594 | | |
| | 5 | 10,458 | 8507 | 8246 | | |

TABLE 35 Relative cost-effectiveness over 20 years for a range of prosthesis costs, revision rates and discount rate in a recipient aged 40 years

dramatically) over time. Increases in revision rates to levels above those assumed will increase total expected costs. Cost-effectiveness rankings will also be changed if rates of revision of prostheses change relative to each other.

The model also assumes that individuals who have had a hip replacement have a mortality rate equal to the general population for their age group. If, however, as studies suggest, these individuals have on average a lower life-expectancy, total expected costs would be lower than estimated here because of the greater number of individuals dying before their prosthesis needs replacing.

Increases (decreases) in prosthesis costs used will increase (decrease) total expected costs. Changes in prosthesis prices relative to each other may also change relative cost-effectiveness. Costs at specific hospitals can be modelled to allow for differences in purchaser prices.

The model does not calculate costs occurring after 20 years, although the present value of future costs is reduced by the discount rate.

The general conclusions under the assumptions of this model are summarised below.

- Compared with Charnley prosthesis survival data from centres of excellence and a prosthesis cost of £353 including cement, the model suggests that a no revisions prosthesis should cost not more than about £650 to have equivalent total expected costs over 20 years (*Table 25*).
- Given the hip survival data used in the model, the Stanmore prosthesis appears to be more cost-effective over 20 years than the Charnley

prosthesis; the Exeter Polished and Müller straight stem are of similar cost-effectiveness (*Tables 27* and *29*).

- Prosthesis cost, hospital costs and revision rate are the components of the model that have the biggest impact in terms of changing total expected costs (*Tables 31* and *32*).
- Very high and very low estimates of hospital costs change the total expected costs of individual prostheses but have little effect on their relative cost-effectiveness (*Table 33*).
- In 70-year-old (men), a low price prosthesis is generally more cost-effective than a high price prosthesis, even with a very low revision rate (*Table 34*).

• In 40-year-old (men), prostheses with high prices and low revision rates can be more cost-effective than low priced prostheses with higher failure rates (*Table 35*).

Despite data of variable quality, and limited data on important characteristics such as longterm survival of prostheses, the approach based on total expected costs enables robust conclusions to be drawn on choice of prostheses. This approach also enables new prostheses to be assessed against those for which good data are available. The model allows new assessments to be made relatively easily as new data become available.

Chapter 12 Conclusion

ealth technology assessment deploys the D perspectives and techniques of different scientific disciplines in order to produce researchbased information of relevance to policy-making and practice in the health service. This review has employed health economics and systematic critical review of clinical research to examine the issues of costs and outcomes of hip prosthesis implantation. Clinical decisions of surgeons as to the choice of prosthesis for given patients take place in the context of a range of other factors beyond the evidence regarding optimal outcomes. These include, for example, the presumed ease of a revision operation offered by different technologies, and a surgeons' familiarity with certain models and the associated surgical techniques (with regard to the latter, for example, the newer cementation techniques are reported to have diffused relatively slowly into THR practice in the UK¹²⁷).

The culture of the manufacture and clinical application of hip prostheses is characterised by a high level of innovation and experimentation. New models are proliferating and many of the new models are also among the most expensive. Clinical outcomes during early postoperative follow-up are unreliable as guides to future performance. This means that comparative performance is difficult to evaluate. The cost of the prosthesis is a significant component of the total cost of the THR procedure.

A full policy analysis of the options for containing costs and maintaining or improving quality of hip prosthesis performance is beyond the scope of this report. It can be noted that a surveillance scheme for hip implants, based on the concept of a 'recommended list', was agreed in 1981 but not implemented. There are a number of possible avenues, not necessarily mutually exclusive, which might be considered in a policy appraisal. These include:

- the concept of the lifetime care package for healthcare commissioners, which includes a quality incentive for the prosthesis supplier and an insurance element for the clinical service provider and healthcare commissioner,¹¹⁶ discussed in the context of the economic model presented in this report
- nationally co-ordinated audit and the use of registers such as those employed in the Scandinavian countries
- the role of the national Medical Devices Agency, providers and purchasers specifically in requiring reports of adverse incidents and generally in the use of mechanisms for monitoring outcomes in terms of hip scores and prosthesis longevity
- implant standardisation programmes,¹²⁸ which can show cost savings and quality maintenance using patient scoring systems to match prosthesis type to expected demand placed upon the prosthesis
- use of competitive bidding practices by hospitals or consortia
- restriction of substantially new technologies to high-quality multicentre controlled trials
- audit of standards of surgical training and experience, especially with newer types of prosthesis which require familiarity with new instrumentation and techniques.

Improving effectiveness and cost-effectiveness of total hip prostheses requires major commitment from the many disciplines involved in health technology assessment in this area, and the health service and policy users of these assessments.

Chapter 13 Summary and recommendations

I n this summary the findings of our review of evidence and the main results of our economic model in estimating the cost-effectiveness of alternative hip prostheses are presented. It includes recommendations for future research and suggestions regarding THR policy in the NHS. Policy options relating to monitoring, innovation and the diffusion of hip prosthesis technology were suggested in the previous chapter, although a full and detailed consideration of these awaits further dedicated investigation.

Clinical research on hip prosthesis technology

- Clinical outcomes of THR are measured by prosthesis survival, radiographic measurement and hip scoring. Clinical hip scoring performed by clinicians is likely to underestimate the qualitative significance of pain and functional impairment for patients receiving hip implants.²⁸ Incorporation of patient perspectives is inadequate. Different studies define clinical outcome measures in somewhat different ways, making comparison of studies difficult.
- The great majority of studies appear in a small number of specialist orthopaedic journals and emanate from specialist orthopaedic centres and departments, mainly in teaching hospitals. This has a bearing on the generalisability of the results of individual studies. The cemented Charnley prosthesis is the most studied single model.
- About 12% of the reviewed studies originate in the UK. Length of follow-up is inadequate for the full evaluation of the longevity of more recently introduced types of prosthesis. Evidence for association between early radiographic signs of loosening and migration and long-term prosthesis survival is equivocal, although there is some evidence that early radiographically defined failure predicts later requirement for revision of the prosthesis.
- The majority of studies of the outcomes of hip prostheses in primary THR are observational in design. Few RCTs have been published. This review maximises the use of studies with an element of comparison between prosthesis types.
- Critical appraisal of relevant studies shows that, with some exceptions, the methodological quality of studies is generally poor. Especially

notable is the lack of reporting of a sample size calculation in any of the reviewed studies. Sample sizes actually reported in most studies are notably smaller than would be recommended to achieve valid generalisable results.

• Given the generally poor methodological quality of the reviewed studies, results for different types of prostheses should be treated as estimates with wide confidence intervals.

Comparative evidence for hip prosthesis technologies

Taking the above points into account, the following conclusions can be drawn about the performance of different types of prosthetic hip technology on the basis of this review. (Definitions of the different types of prosthesis can be found in chapter 3.)

- **Cemented** designs in general show good survival results at 10–15 years and beyond. Models with good, published, comparable results (at 10 years or more) include the Stanmore, Howse, Lubinus, Exeter and Charnley. The rate of acetabular revision in cemented implants remains problematical. There is some evidence that allpolyethylene acetabular components are preferable to metal-backed designs in terms of longevity of the implant. Newer (second-generation) cementation techniques in general provide better results than traditional techniques.
- Evidence of short- to medium-term comparisons of prosthesis longevity between **non-cemented porous-coated** designs and **cemented** designs is equivocal. The first 10-year survival results for porous-coated models appear to bear comparison with the cemented models after the same followup period, especially taking into account the relatively lower average age of the patient groups implanted with the porous-coated models. One comparative radiographic study suggests that cemented acetabular components performed better than porous-coated designs but that porous-coated stems performed better than cemented models.
- The comparative evidence suggests strongly that thigh pain is a problem associated with **cementless porous-coated** implants, to which **cemented** designs are not prone. In the observational studies of porous-coated implants reviewed here,

reports of its prevalence range from about 2% to about 25% at 2–7 years follow-up, with several studies reporting prevalences around the higher 25% level, even in non-loose stems.

- In contrast to porous-coated models, the small number of studies of **cementless HA-coated** models report mild to moderate thigh pain ranging from 0% to about 5% of patients at 2–5 years follow-up. This is a relatively good result in comparison to reports of porous-coated implants and requires further investigation.
- Radiographic studies of **cemented** versus **HA-coated** designs suggest that HA-coating has better early fixation and less migration than cemented models. The lesser migration of HAcoated models may be associated with less early postoperative pain, according to one comparative study. However, with maximum follow-up periods of only 3–4 years for this form of fixation, longer-term study of survival and clinical results is required.
- **Hybrid** prostheses appear to do well in the short term but the available studies cannot give any indications for their mid- or long-term performance. Given wide confidence intervals, this type of design can be regarded as comparable with the best cemented designs for early (6–7 years) survival. Their early survival is superior to uncemented porous-coated implants, and early thigh pain in cemented stem components in hybrid implants is minimal or absent compared with porous-coated designs. Longer follow-up, especially of the coated acetabular component of hybrid implants, is required to ascertain the medium and long-term performance of this design.
- Little evidence is available about **fully modular** prostheses. Theoretically, modularity permits greater intra-operative flexibility for the surgeon and potentially better component fit but further evidence, especially comparison with cemented implants, is required. One comparative study suggests that a fully modular stem has performed less well than cemented stems. Laboratory analysis of retrieved components suggests that mixed-alloy components are more prone to corrosion than single alloy devices.²⁹
- The implications of laboratory studies of alternative bearing surface materials require further assessment. The small amount of evidence for the performance of hips with **ceramic** bearing surfaces is equivocal. Wear rates are less than for other materials at the articulating surface of the joint. Comparative studies have suggested either lower or equivalent revision rates for ceramic versus cemented implants at medium-term follow-up. Ceramic heads are common, but major manufacturers are currently developing

metal-metal versions of common designs, for which published evidence is lacking.

• The **uncoated press-fit** and **resurfacing** types of hip prosthesis generally have survival results not-ably inferior to the other types of design available.

Economic modelling

• The economic model developed in this study and presented in the report can be used to model the cost-effectiveness of different hip prostheses under any different resource and clinical outcome assumptions which healthcare practitioners and decision-makers might foresee.

The general conclusions under our assumptions used in this model are summarised below.

- Prosthesis cost, hospital costs and the revision rate are the components of the model that have the biggest impact in terms of changing total expected costs for THR procedures.
- Very high and very low estimates of hospital costs change individual prostheses' total expected costs but have little effect on their cost-effectiveness relative to each other.
- Compared with survival data for the Charnley cemented prosthesis from centres of excellence, and assuming a prosthesis cost of £353 including cement, the model suggests that even a no revisions prosthesis should cost no more than about £650 currently (1997 prices) to have equivalent total expected costs over 20 years. Only cemented prostheses are currently available at this price.
- In 70-year-olds (men), a low price prosthesis is generally more cost-effective than a high price prosthesis, even with a very low revision rate.
- In 40-year-olds (men), prostheses with high prices and low revision rates can be more cost-effective than low-priced prostheses with higher failure rates.

Policy/service implications

The authors suggest that:

- mechanisms for improving support for the use of appropriate prostheses could be examined in a wide-ranging policy analysis, to include combinations of local contracting, coordinated audit or monitoring, central UK registers, and regulation of new technologies via coordinated trials
- healthcare commissioners could consider modelling costs of alternative prosthesis designs and

models using their own local input resource assumptions and outcome data, along the lines of the model demonstrated in this report.

Given the variation in effectiveness of prosthesis types, the authors suggest that commissioners and providers could consider the following monitoring issues when developing policy.

- The range and extent of use of prostheses known to have results poorer than the best cemented designs, such as the Stanmore, Howse, Lubinus, Exeter and Charnley prostheses.
- In the case of substantively new designs, appropriate monitoring and evaluation (including cost dimensions) prior to diffusion into routine practice.
- The extent of implantation of different design types (such as cemented, hybrid, porous) in relation to age-groups of patients, seeking audit of clinical and patient outcomes.
- Routine rates for different types of prosthesis including revision (and re-revision) rates – as proportions of total THR rates for the provider/ NHS Trust, taking into account status as general or specialist tertiary referral centres.

Recommendations for further research

General

- Improvements should be sought in the design and reporting of the generality of research studies in this area. Notable aspects are sample sizes, reporting of data on characteristics of the study group or groups, use of blinding or independent evaluation as appropriate, and reporting of patient selection criteria and procedures.
- Further inclusion of patient-derived qualityof-life measures in studies of hip prosthesis performance is essential. Clinical hip scoring systems do not take account of the patient's point of view in assessing outcomes.
- Further review from existing studies of shortterm hip score outcomes could yield valuable information about pain and everyday activity during the early 'settling down' postoperative period, which appears to vary between different types of prosthesis.
- The existing clinical research on THR assumes that given tolerable pain and physical function, longevity of the implant is the primary goal. This may be the case from the patients' perspective also but this has not been demonstrated. If ease of revision were an important criterion

from the patient's perspective as well as from the surgeon's then the choice of implant would be affected. Patients' values and choices regarding quality of life in relation to the perceived risk of undergoing a revision operation should be investigated. This applies especially to younger and/or more active patients for whom revision is more likely.

- There is scope for review of further good quality studies, not included in this review, on the mechanics of loosening in different types of prostheses.
- New primary studies of the mechanics of loosening could employ radiographic techniques and/or autopsy limb retrieval approaches.

Prosthesis types

- Reporting of longer follow-up studies especially of the hybrid and cementless HA-coated models is required in order to assess further the early promising outcomes of these technologies. Longer follow-up of the coated acetabular component of hybrid implants is required to ascertain the medium and long-term performance of this design.
- Results for thigh pain in HA-coated models appear relatively good in comparison to reports of porous-coated implants, and this requires further examination for longer followup periods. The extent and significance to patients of thigh pain associated with porousand HA-coated implants should be assessed.
- The implications of laboratory studies of alternative bearing surface materials require further review and investigation.
- Porous-coated cementless designs should be monitored further where already implanted to assess longevity.
- Fully modular designs may offer advantages in surgical procedure but the lengths of follow-up are currently insufficient to establish patient benefits or problems of this type of design.
- In the past there has appeared to be reluctance, inertia or lack of resources in many orthopaedic departments in the UK to adopt new cementation techniques for cemented prostheses.¹²⁷ More recent information is required on the use of these methods so that, given the better outcomes generally associated with them, their use can be encouraged.
- Further exploration is required of associations between radiographic signs of loosening/ migration and later mechanical failure of different designs. Insufficient data exist on the predictive power of radiographic measurements.

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Studies appraised in the review

Studies appraised in this review are listed, in alphabetical order of author, by type of study design. While some of them have also been listed numerically in the main reference list, all of these studies are included in the Data Tables and Appraisal Tables in the appendix.

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Appendix I Data tables and appraisal tables

The Data Tables, which include data extracted from all the studies included in this review, and the Appraisal Tables, the detailed checklist-based appraisals of these studies, form the major part of this appendix.

However, given the high value placed upon – and the relative scarcity of – RCTs in the scientific orthopaedic literature on hip prostheses, a brief summary of each of the RCTs included in this review is presented first. Details of the critical appraisal of each are in the appraisal tables. Studies with reference numbers are mentioned in the main text.

Individual summaries of RCTs

Bourne and colleagues, 1995;45 Rorabeck and colleagues, 199646

There have been a number of reports of this patient population. These two papers present the most recent results.

All patients were operated on or supervised by two senior surgeons using the Mallory Head prosthesis, either cemented or press-fit. Originally 250 patients were recruited from a group with an age range of 18–75 years, and were stratified by age and surgeon. Diagnosis was primary or secondary osteoarthritis of the hip without additional life threatening illnesses. Results of clinical aspects were reported with a 5-year follow-up (number of patients not stated) and for radiographic analysis with a 4-year follow-up (147 patients). Patients and clinical observers were blinded. All clinical assessments (for example, Harris Score, d'Aubigne Score and Sickness Impact Profile) were almost identical for each group both pre- and postoperatively. There was no subsidence in the cemented stems but 14% of press-fit stems subsided by 3-5 mm. No revisions were required within the 4 years and no press-fit components or cemented stems were loose; however, 26% of the cemented cups were termed definitely or probably loose. C-rated.

Bradley and Ledd, 1992³⁴

In this study the Furlong (HA-coated prosthesis, n = 97) was compared with the Charnley (n = 73).

The patients (with primary osteoarthritis and of average age 68 years, range 45–75 years) were randomly allocated by year of birth, even numbered years to the Furlong, odd numbers to the Charnley (any patient technically unsuitable for the HA-coated prosthesis were excluded irrespective of their year of birth). This paper reported on 139 patients with follow-up of 1 year and 74 patients with 2 years. Patients were seen preand postoperatively at their homes by a nurse practitioner, radiographic assessment took place at hospital at similar time intervals. The results at 1 year and 2 years were very similar in both groups (that is, numbers with no pain or limp, walking distance and use of walking aids, ability to climb stairs and put on shoes/socks). No patients were lost to follow-up but two in each group died of unrelated causes. There were no revisions or evidence of loosening. C-rated.

Carlsson and colleagues, 1995

Originally 352 patients were included in this study from five Swedish orthopaedic departments (separate randomisation was performed at each centre, where surgical approach and prosthesis type differed). Those with radiographic loosening and diagnoses other than primary arthrosis were excluded (among others) leaving 190 hips. Three of the prostheses studied had a large collar (Lubinus, Harris Design 2 and Scanhip) while the Exeter and Charnley were collarless. Resorption of the resected femoral neck was more often observed in prostheses with a true collar (odds ratio at 5 years postoperatively 4.1, p < 0.001) and to a greater extent (p < 0.001). No details were given either of the patients or if the assessments were performed blindly and/or independently of the operating surgeon. C-rated.

Ciccotti and colleagues, 1994

Primary cementless THRs were inserted into 60 patients with osteoarthritis (mean age 63–66 years). They were matched for age and weight prior to randomisation (no details) to HA- or porous-coated Taperloc prostheses **and** to postoperative weight-bearing status (at 6 or 12 weeks), thus giving four groups. Eight 0.8 mm tantalum markers were also positioned in the bone during the operation. All patients were assessed after 2 years. No differences were found between the groups either relating to the coating on the prostheses or to the timing of weight-bearing status as measured by Charnley scores (pre- or postoperatively) or by Visual Analogue Scales for thigh pain. Migration was less than 1.40 mm in all groups and no revisions were reported to be necessary within the 2 years. **C-rated.**

Godsiff and colleagues, 1992²⁵

In this study 30 cemented were compared with 28 cementless femoral components (Ring prosthesis) in patients with an age range of 55-74 years and a diagnosis of primary osteoarthritis of the hip only. Patients were assigned to a group by choosing one out of two envelopes themselves and were blinded to the result. Surgery was by one of two surgeons and the clinical assessment was by an independent, non-orthopaedic medical practitioner. At 2 years the two groups (n = 47) reported a similar pain incidence, the cementless group having had more pain at 4 and 12 months. By 2 years 96% cemented and 62% cementless did not require walking aids (p, 0.01–0.05). Preliminary results seemed to indicate cemented to be superior to cementless; however, because of unacceptable levels of femoral breakages at 3–5 years, the authors withdrew the prosthesis. A-rated.

Jacobsson and colleagues, 1994114

Two senior surgeons operated on 56 patients (24 women, 32 men, mean age 52 years) of whom 75% had a diagnosis of osteoarthritis, the remainder having various reasons for the unilateral hip operation. Patients were matched in pairs for sex, age, weight and radiographic appearance before being randomly selected (no details of method) to have a Butel (stem made of four rods for flexibility) or a PCA (rigid) stem (three different press-fit cups were used). Each pair was operated on by the same surgeon and were followed-up for 3 years. The PCA stem gave better results as assessed by Harris Hip Scores (mean 94.4 compared with 78.5 for Butel, *p*-value not given) and the number of prostheses definitely or probably loose (PCA 18%, Butel 86%). Both groups required three hip revisions because of loosening (one further Butel hip was revised for other reasons). **C-rated.**

Karrholm and colleagues, 1994b⁴²

A computer program was used to randomly allocate the 64 patients (age range 58–66 years) to three study groups. The patients were stratified by age, sex, weight, bone quality and diagnosis (primary or non-inflammatory secondary osteoarthritis). The hips had the Ti-Fit femoral component inserted with a press-fit acetabular component by one of four surgeons in one of two hospitals. The femoral stems were inserted with either cement (n = 20), an HA-coating (n = 23) or were porous-coated (n = 21). Six 0.8 mm tantalum markers were inserted into the femoral component. After 2 years the cemented and porous-coated stems had subsided more than the HA-coated (p = 0.002 and 0.02, respectively). The HA-coated components also rotated less than the cemented stems (p = 0.03). The Harris Hip and Pain Scores did not differ significantly between the groups. Pain or discomfort in the thigh was reported in two cemented, five HA-coated and eight porous-coated prostheses (p = ?). There were no revisions within the 2 years. **C-rated**.

Kelley and colleagues, 1993

A total of 84 hips in 84 patients were randomly assigned a Harris Design 2 prosthesis either with (n = 44) or without (n = 40) a collar (method of randomisation not described). The operations were performed by two surgeons. After an average follow-up period of 4.6 years (range 2-7 years) 32 patients with collarless (mean age 70 years) and 38 with collared prostheses (mean age 68 years) were available for study (six patients died from unrelated causes). Patient diagnosis was mainly degenerative joint disease (79%). Postoperative pain and mobility levels were similar in the two groups as were the Harris Hip Scores. The amount of migration or radiolucency at the bone-cement interface did not differ significantly between them but the collar seemed to alter subsidence in the hips (mean 0.5 mm, as opposed to a mean of 2 mm for the collarless prostheses, p < 0.05). In all, 5% of collared and 9% of collarless prostheses required revision because of aseptic loosening of the femoral component (p = ?). **C-rated.**

Krismer and colleagues, 1994

In this study, migration was compared in two acetabular components - RM cup (HA-coated with a CLS stem) and PCA cup (porous-coated with a PCA stem). The patients (age range 50–65 years) were stratified by age and the two surgeons prior to randomisation and were followed for 5.2 years (mean). Diagnosis was primary or secondary osteoarthritis only. Almost one-third of the patients were lost or excluded from radiological assessment and almost half were not clinically evaluated. The Standard System of Terminology for Reporting Results (SSTRR) was used to compare clinical findings such as Pain (no/mild pain: RM 94%, PCA 97%; p = 0.05) and Limp Without Support (no/slight limp: RM 90%, PCA 55%; *p* = 0.02). Migration assessment found greater longitudinal movement in the PCA cup. As loosening was defined as

> 1 mm longitudinal migration, 12% RM and 27% PCA cups were termed loose (p = 0.08). **C-rated.**

Marston and colleagues, 1996¹⁰⁷

Random number tables were used to assign 213 patients to a Stanmore prosthesis and 200 to a Charnley hip. For the 53 bilateral operations the second hip was also randomised giving 14 patients with two different prostheses. The mean age of the 360 patients (126 men, 234 women) was 67 years and > 85% had primary osteoarthritis. Various surgeons at various grades performed the operations using three different approaches. The mean follow-up period was 6.5 years (range 5-10 years; 76 patients died and two were lost to follow-up) and the hips were reviewed by an independent observer. There were no differences in Harris scores between the groups either pre- or postoperatively. Three Stanmore and four Charnley stems were asymptomatically loose (the Stanmore had radiolucent lines > 2 mm around the component). Revision rates did not vary greatly between the prostheses (4.2% Stanmore, 3.5% Charnley). However, the relative risk of requiring revision was found to be 11.47 times greater for trainee compared with qualified surgeons. C-rated.

Olsson and colleagues, 1985³⁸

A total of 119 patients had either a cemented (Charnley, n = 61) or uncemented (Honnart Patel-Garches, n = 59) prosthesis implanted. The mean ages of the patients were 67 years and 64 years, respectively; 82% had a diagnosis of osteoarthritis and 10% of rheumatoid arthritis (with the remainder miscellaneous). The number and grade of surgeons was not specified. Clinical evaluation showed similar preoperation results but the Charnley prosthesis performed better at the 1 year assessment - Harris Hip Score and Limp (Charnley vs. Honnart Patel-Garches) p < 0.001; maximal walking speed (Charnley vs. Honnart Patel-Garches) p < 0.05 (twice as many patients fitted with the latter device required an ambulatory device). A quantitative analysis of gait showed the Honnart Patel-Garches group to have slightly better preoperative results but 1 year after surgery the Charnley group showed greater improvement. No revisions were reported. C-rated.

Onsten and Carlsson, 1994

As a result of primary arthrosis, 60 patients (age range 40–70 years) had a unilateral hip replaced. A computer program randomised them to either a cemented, all polyethylene Charnley socket (n = 30) or a cementless, porous-coated Harris-Galante type 1 socket (n = 30). Any unstable screws were removed from the Harris-Galante prosthesis during the original operation (this did not affect subsequent results) and between five and ten 0.18 mm tantalum markers were inserted into the pelvis and socket of both types to aid movement analysis during the 2-year follow-up period. There were no revisions reported. Harris Hip and Pain Scores did not differ between the groups. There were no overall differences in either migration or rotation in any axis by 2 years but 15/27 (55.5%) Charnley and 28/30 (93.3%) Harris Galante sockets displayed "significant" movement at 2 years (p = 0.001). **C-rated.**

Onsten and colleagues, 1994³⁵

Charnley femoral components were inserted bilaterally, under the same anaesthesia, into 29 patients with primary osteoarthritis by one of three surgeons. A Harris-Galante type 1 acetabular component was randomly implanted in one hip and a Charnley acetabular cemented component into the other. Tantalum balls (0.8 mm diameter) were inserted into the pelvis and acetabular cup during the operation. In all, 21 patients (42 hips) were studied (age range 41-76 years) for an average of 27 months. Five Charnley and three Harris-Galante cups did not move at all. The maximum migration (in any direction) was 1.7 and 2.1 mm, and maximum rotation was 2.2 and 2.0 degrees for the Harris-Galante and Charnley prostheses, respectively. There were no differences in the mean values of absolute migration between the groups in any direction (p = 0.06-0.98) but there were in the mean values of absolute rotation (p = 0.08 - 0.008) – Harris-Galante hips rotating the most. C-rated.

Reigstad and colleagues, 198649

In all, 155 Müller and 149 ICLH prostheses were implanted into 231 patients (age range 60-79 years) by 13 surgeons. All patients in this study were diagnosed with osteoarthritis of the hip (excluding those with heavy bone loss in the femoral head or earlier fracture of the femoral neck) and had a mean follow-up of 48.5 months. No Müller hips were revised as opposed to 8.7% ICLH (p < 0.001), and, in addition, one component (0.6%) was loose compared to 12 (8%), respectively. Postoperatively, the Müller group had consistently higher scores than the ICLH group on all three modified Merle d'Aubigne and Postel parameters and total hip function. This reached a level of significance (p < 0.001) by 1 year in 3/4 parameters. C-rated.

Søballe and colleagues, 1993

Migration of titanium-coated femoral components and HA-coated stems in a Biometric prosthesis

82

were compared in this RCT. The same surgeon performed the surgery on all the patients (aged 48-68 years). The diagnosis was primary osteoarthritis (one patient had secondary osteoarthritis). Radiographic analysis was blinded. All components had migrated by 3 months but by 12 months the titanium-coated stems had migrated further than the HA-coated (p = 0.02), possibly indicating an increased risk of subsequent loosening and revision of the prosthesis. The HA-coated THR was also associated with higher Harris Hip Scores and less pain (measured by Visual Analogue Scale) at 12 months. A problem with the study was that small numbers of patients were involved -12 titanium-coated and 14 HA-coated prostheses were available for clinical and conventional radiographic assessment, and eight and seven, respectively, for roentgen stereophotogrammetric analysis. C-rated.

Thanner and colleagues, 1995¹⁰⁸

This comparison of two cement types – Boneloc and Palacos – involved 30 hips in 30 patients, age range 63–76 years, 27 of whom had primary osteoarthritis. Tantalum markers (0.8 mm) were inserted into the cup of the Spectrum EF prosthesis and the pelvis. Full radiostereometric analysis was possible in only 24 patients at 1 year (one Boneloc patient had died). Palacos fixed cups had 'a small' lateral migration while cups with Boneloc migrated medially (p = 0.03) and proximally (p = 0.04); 1/16 Palacos stems subsided 0.27 mm whilst 6/13Boneloc stems subsided 0.22–1.0 mm (p = 0.005). Increased acetabular radiolucent lines and femoral 'relative cement–cortical bone contact' occurred in the Boneloc group compared with the Palacos group (p = 0.04 and p = 0.03, respectively). Harris Hip and Pain Scores and a Visual Analogue Scale for pain improved postoperatively (p = 0.0004– 0.002) but did not differ between the groups (p, not significant). **C-rated.**

Wykman and colleagues, 1991³⁷

A comparison of cemented (Charnley) and cementless press-fit (Honnart Patel-Garches) fixation in 150 patients; 15 in each group had bilateral arthroplasties (age range 29-82 years; diagnosis 77% osteoarthritis, 10% rheumatoid arthritis, 13% miscellaneous). The two prostheses had a similar probability of survival by 5-6 years approximately (Charnley 88%, Honnart Patel-Garches 82%; p, not significant). More revisions were required in the Honnart Patel-Garches group over 5 years (18.7%, all for loosening, all but one causing mid-thigh pain) compared to the Charnley group (11%, five for loosening, no mid-thigh pain). A further five Honnart Patel-Garches prostheses had possible need for revision due to midthigh pain (increasing the revision rate to 25%). Subsidence of more than 4 mm occurred in 5% of Charnley and 33% of Honnart Patel-Garches prostheses. C-rated.

DATA TABLE 1 RCTs included in the review

| | technique | and number of patients followed-up | variables reported | | |
|--|---|--|---|---|---|
| RCT; cemented (i) vs. press-fit (ii) Mallory Head (i) cemented (ii) cementless (press-fit) | By, or supervised by, two senior surgeons Teaching hospital Direct lateral | (i) 124 in 124 patients (ii) 126 in 124 patients Radiographic data: 4.8 years (range 4-6); clinical data: 5 years 4-year follow-up: (i) 76 patients (ii) 71 patients | Mean age 65 years (at last follow-up; original range 18–75 years) Sex Diagnosis (primary or secondary osteoarthritis with exclusions) | Harris Hip Score (mean): (i) Preoperative, 43; 5 years, 96 (ii) Preoperative, 42; 5 years, 97. d'Aubigne Score: (i) Preoperative, 9; 5 years, 17.4 (ii) Preoperative, 9; 5 years, 17.5. WOMAC: (i) and (ii) Preoperative pain score, 6; 5 years, 1 (similar findings for other WOMAC dimensions). MACTAR Index: (i) Preoperative, 7.8; 5 years, 1 (ii) Preoperative, 7.7; 5 years, 0.67. Sickness Impact Profile – Global Physical Score: (i) Preoperative, 25.2; 5 years, 5.2 (ii) Preoperative, 25.2; 5 years, 5.2 (iii) Preoperative, 0.26; 5 years, 0.76 (ii) Preoperative, 0.26; 5 years, 0.76 (ii) Preoperative, 227 m; 5 years, 392 m (ii) Preoperative, 229 m; 5 years, 409 m; p, not significant. Migration/subsidence: (i) 1 cup migrated; 10 (14%) stems subsided by 3–5 mm. Revisions/loosening: (i) 20 cups definitely/probably loose (26.3%); no stems loose; no revisions (ii) no revisions; no components loose. | C |
| RCT; HA (i) vs. cemented (ii) (i) Furlong (ii) Charnley | Not stated General hospital Antero-lateral | 163 patients followed-up for maximum 2 years I-year follow-up 139 patients 2-year follow-up 74 patients | Mean age 68 years (range, 45–75) Primary osteoarthritis (only those who were suitable for cementless prostheses) | Based on Harris Hip Scores: No pain: (i) 98% (ii) 96%; $p = ?$ Absence of limp, walking aids used, walking distance, stairs, movement: uniformly good average results ($p = ?$). No revisions or radiographic evidence of loosening. | С |
| RCT; all cemented (i) Charnley (no collar) (ii) Exeter (non-polished; no collar) (iii) Lubinus SP (collar) (iv) Harris Design 2 (collar) (v) Scanhip (collar) | Not stated | 352 190 followed-up for 5 years, as follows: (i) 57 (ii) 58 (iii) 33 (iv) 16 (v) 26 | Not specified | Resorption of the resected femoral neck: patients: (i) 19% (ii) 19% (iii) 42% (iv) 56% (v) 54%). (Odds ratio, 4.1; $p < 0.001$; more often seen in those with true collar. Amount of resorption is also larger ($p < 0.001$).) | C |
| | RCT; HA (i) vs. cemented (ii) cementless (press-fit) RCT; HA (i) vs. cemented (ii) (i) Furlong (ii) Charnley RCT; all cemented (ii) Charnley (iii) Charnley (iii) Charnley (iii) Charnley (iii) Lubinus SP (collar) (iv) Harris Design 2 (collar) | Mallory Head (i) cemented (ii) cementless (press-fit) Teaching hospital Direct lateral Direct lateral Direct lateral RCT; HA (i) vs. cemented (ii) Not stated (i) Furlong (ii) Charnley Not stated RCT; all cemented Not stated General hospital Antero-lateral RCT; all cemented Not stated (i) Charnley Antero-lateral RCT; all cemented Not stated (i) Charnley Antero-lateral (ii) Lubinus SP (collar) Vot stated (ii) Lubinus SP (collar) Joinus (iii) Lubinus SP (collar) Joinus (iii) Lubinus SP (collar) Joinus (v) Scanhip Joinus | Mallory Head (i) cemented (ii) cemented (ii) cementelss (press-fit) Teaching hospital Direct lateral Radiographic data: 48 years (range 4-6); clinical data: 5 years (i) Cementeds (press-fit) Direct lateral Radiographic data: 10 years (range 4-6); clinical data: 5 years (ii) cementeds (iii) cemented (iii) Not stated 163 patients followed-up for maximum 2 years (ii) Furlong (ii) Charmley Not stated 163 patients followed-up for maximum 2 years (iii) Charmley Antero-lateral 1/2 patients (iii) Charmley Not stated 1/2 patients (iii) Charmley Antero-lateral 1/2 patients (iii) Charmley (i) 57 1/90 followed-up for maximum 2 years (iii) Charmley (i) 57 1/2 patients (iii) Lubinus SP (collar) (i) 57 (ii) 33 ((iii) 33 ((ollar) (iv) Harris Design 2 (collar) (iv) 16 (v) 26 (v) 26 | Mallory Head (i) cemented (i) cemented (i) cementeds (i) cementess Teaching hospital Direct lateral Radiographic data: 4.9 years (range 4-6); clinical data: 5 years 4.year follow-up: (i) 76 patients (ii) 71 patients Sex Diagnosis (primary or secondary) Diagnosis (primary or secondary) Sex Diagnosis (primary or secondary) RCT; HA (i) vs. cemented (ii) (i) Charnley Not stated General hospital Antero-lateral I63 patients followed-up for maximum 2 years Mean age 68 years follow-up; osteoarthritis with exclusions) RCT; all cemented Not stated (i) Charnley Not stated (i) Charnley I63 patients followed-up for maximum 2 years Mean age 68 years follow-up; osteoarthritis 2-year follow-up 139 patients Mean age 69 years (in y these who were subble for cementes prosthese) RCT; all cemented Not stated (i) Charnley (ii) Exteref (non-polished; no collar) 352 Not specified (ii) Charnley (iv) Harris Design 2 (collar) 190 followed-up for 5 years, as follows: (ii) 33 (iv) 16 (iv) 42 S52 | Mallory Had (i) canneted (i) canneted (ii) canneted (iii) canneted (iiii) canneted (iii) canneted (iii) canneted (iii) canneted (iii) ca |

| DATA TABLE 1 cont | RCTs included | in the review |
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|-------------------|---------------|---------------|

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
|---|---|---|---|---|--|------------|
| Ciccotti, et <i>al.,</i> 1994 (USA) | RCT; HA vs. porous-coated Porous taperloc design: (i) HA-coated, 12-weeks post- operative weight bearing (PWB) (ii) porous- coated, 12-weeks PWB (iii) HA-coated, 6-weeks PWB (iv) porous- coated, 6-weeks PWB HA versus porous-coated | Grade not specified, but by or super- vised by three MDs Teaching and general hospital Lateral with trochanteric osteotomy | 60 in 60 patients 60 followed-up for 2 years | Mean age: (i) 66.3 years (ii) 66.2 years (iii) 63 years (iv) 63 years Weight Osteoarthritis | Charnley scores: Preoperative – no significant differences between groups for pain, function or motion; Postoperative – no significant difference in pain, function and motion at 2 years. Visual Analogue Scales for thigh pain: No significant difference between groups (2 years). Migration: No significant difference between groups – less than 1.40 mm for all groups. No revisions reported. | С |
| Godsiff, et al., 1992 (UK) | RCT; cemented (i) vs. press-fit (ii) Ring Stem – (i) cemented (ii) cementless + cementless cup | Two consultants General hospital (?) Posterior | 58 in 54 patients: (i) 30 (ii) 28 Followed-up for 2 years maximum (i) 23 (ii) 24 | Age range 55–74 years; mean (i) 64.4 (ii) 64.5 Diagnosis (primary osteoarthritis of hip only) Sex | Authors' own 5-point scale: Pain and mobility (at 2 years) – (i) 15 pain free with no restriction (ii) 15 pain free with no restriction. Use of walking aids: (i) 22 (96%) did not use any aids (ii) 15 (62%) did not use any aids (p, 0.01–0.05). NB: At 3–5 years there were an unacceptable number of stem breakages; discontinued prosthesis use. (see Wilson, et al., 1992 in RCT reference list). | Α |
| Jacobsson, et al., 1994 (Sweden) Unusual (Previous report: Jacobsson, et al., 1993) | RCT; Isoelastic (i) vs. porous- coated (ii) (i) Butel stem (ii) PCA stem plus PCA, Ti-Fit or Romanus cup | Two senior surgeons Teaching hospital Dorsolateral | (i) 28 (28 patients) (ii) 28 (28 patients) Follow-up 3 years (i) 27 (ii) 26 | Mean age 52 ± 8 years Sex Weight Radiographic appearance | Harris Hip Score: (i) +3 years, mean 78.5 (42–100) (ii) +3 years, mean 94.4 (59–100) p = ? Loosening: (i) 24/28 (86%) loose or possibly loose (ii) 5/28 (18%) loose or possibly loose p = ? Revisions: (i) 4 (14.3%), 3 due to loosening (ii) 3 (10.7%), all due to loosening. | С |
| Karrholm, et al., 1994 (Sweden) | RCT; cemented (i) vs. HA-coated (ii) vs. porous- coated (iii) Ti-fit Press-fit cup plus: (i) cemented stem or (ii) HA-coated stem or (iii) porous- coated stem | Three MDs + one other (not specified) Teaching hospital Posterior or lateral | (i) 20 (ii) 23 (3) 21 in 60 patients Followed-up for 2 years 64 hips, 60 patients | Mean age (range): (i) 50 years (38-66) (ii) 56 years (38-63) (iii) 55 years (45-63) Sex Weight Diagnosis Bone quality index | Harris Hip Score (medians): (i) Preoperative, 43 (21-58); +2 years, 96 (64–10 (ii) Preoperative, 48 (14-67); +2 years, 95 (63–10 (iii) Preoperative, 39 (18-62); +2 years, 94 (66–10 p, not significant. Harris Pain Score: (i) Preoperative, 10 (0–20); +2 years, 44 (30–44) (ii) Preoperative, 10 (0–30); +2 years, 40 (20–44 (iii) p.not significant. 33 hips (31 patients), no or slight pain Thigh pain (pain or discomfort in the thigh): (i) 2; (ii) 5; (iii) 8; p , ? Migration of centre of stem (minima/maxima): (i) $-0.8; -0.3$ mm (ii) $-1.2; -0.8$ mm (iii) $-2.7; -0.3$ mm (i) & (iii) subsided more than (ii); (i) vs. (ii) p , 0.002; (ii) vs. (iii) p , 0.02. Rotation (median absolute value of anterior- posterior tilt about the transverse axis): (i) 0.4; (ii) 0.2; (iii) 0.4 degrees (i) vs. (ii) p , 0.03; (ii) vs. (iii) p , 0.07. No revisions. | 00) 00) |

DATA TABLE 1 contd RCTs included in the review

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|--|---|---|---|--|---|----------|
| Kelley, et al., 1993 (USA) | RCT; cemented Harris Design 2 (i) with collar (ii) collarless | Two surgeons, grades not specified Not specified | 84 in 84 patients Mean follow-up 4.6 years (range 2–7) 70 (i) 38, (ii) 32 | Mean age (i) 67.7 years (± 7.7) (ii) 69.6 years (± 9.7) Sex Weight Previous surgery Diagnosis | Pain: (i) No/slight pain, 33/38 (87%) (ii) No/slight pain, 27/32 (84%) p, not significant. Activity patterns: (i) Able to ambulate unlimited distances, 17/38 (45%) (ii) Able to ambulate unlimited distances, 14/32 (44%) p, not significant. Harris Hip Score (mean): (i) 89.5; (ii) 86.7; ($p > 0.05$). Migration: no significant differences in movement or bone-cement interface radiolucency between groups. Subsidence: (i) Mean 0.5 mm (\pm 1.5); (ii) Mean 2 mm (\pm 4); ($p < 0.05$). Revisions/loosening: (i) 2 (5.3%) revisions due to loose stems (ii) 3 (9.4%) revisions due to loose stems p,? | C |
| Krismer, et <i>al.</i> , 1994 (Austria) | RCT; HA (i) vs. porous- coated (ii) (i) RM cup (+ CLS stem) (ii) PCA cup (+ PCA stem) | Two 'experienced surgeons' Teaching hospital Anterolateral | (i) 61 (ii) 59 Follow-up: maximum 6 years; mean 5.2 years Clinical assessment: (i) 31 (51%) (ii) 33 (56%) Radiological assessment: (i) 42 (69%) (ii) 45 (76%) | Mean age (SD): (i) 58 years (4) (ii) 57 years (5) Sex Primary or secondary osteoarthritis | SSTRR system – Pain: (i) No/mild pain, 29 patients (94%) (ii) No/mild pain, 32 patients (97%) p, 0.05. SSTRR system – Limp without support: (i) No/slight limp, 28 patients (90%) (ii) No/slight limp, 18 patients (55%) p, 0.02. Migration: (i) Longitudinal: mean 0.05 mm; maximum mediolateral 0.10 mm; medial > 2 mm – 2 cups (ii) Longitudinal: mean 0.34 mm; maximum mediolateral 0.04 mm; medial > 2 mm – 2 cups. Revision/loosening: 3 revisions: 1 septic loosening, 2 CLS stems revised (i) 5 (12%) cups loose (ii) 12 (27%) cups loose p, 0.08. | |
| Marston, et <i>al.,</i> 1996 (UK) | RCT; cemented (i) Stanmore (ii) Charnley | Various grades of surgeon General teaching unit 54% anterolateral; 40–42% McFarland- Osborne; 4–6% posterior | 413 hips in 360 patients) (i) 213 hips (ii) 200 hips (53 patients bilateral – 14 had two different prostheses) Follow-up, 5–10 years (mean 6.5) 413 hips (59 by questionnaire/interview, 78 patients by last clinic visit) | Mean age = 67 years (male range 18–91) (female range 30–87) Sex Diagnosis | Harris score: (i) Preoperative, 46.0; postoperative, 91.4 (ii) Preoperative, 46.0; postoperative, 91.2 p, not significant. Asymptomatic loosening (radiolucent lines > 2 mm): (i) 3 stems and corresponding cups (average subsidence for 57 stems at 7 years, 2.8 mm) (ii) 4 stems and corresponding cups (average subsidence for 51 stems at 7 years, 2.6 mm) p, not significant. Revisions (all for suspected loosening): (i) 9 (4.2%; 1 cup, 2 both, 5 stems, 1 exploration) (ii) 7 (3.5%; 5 stems, 1 both, 1 no details); relative risk of requiring revision 11.47 times greater for traines (95% Cl, 1.53–86.06); odds ratio for revision, 0.82 for (ii) vs. (i) (95% Cl, 0.27–2.47). | C |
| | | | | | | continue |

DATA TABLE 1 contd RCTs included in the review

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|---|--|--|---|--|--|---------|
| Olsson, <i>et al.,</i> 1985 (Sweden) | RCT; cemented (i) vs. press-fit (ii) (i) Charnley (ii) Honnart Patel-Garches | Not specified General hospital (i) anterolateral with trochanteric osteotomy (ii) posterior without trochanteric osteotomy | (i) 61 in 61 patients (ii) 58 in 58 patients Follow-up, 1 year (i) 60–61 (ii) 55–58 (depends on assessment) | Mean age: (i) 67 years (ii) 64 years Sex Weight Height Diagnosis | Harris Hip Score: (i) Preoperative, 40; at 1 year, 89 (ii) Preoperative, 40; at 1 year, 78 Preoperative, p , not significant; at 1 year $p < 0.00$ Limp (moderate/severe): Preoperative: (i) 92%; (ii) 93%; p , not significant Postoperative: (i) 20%; (iii) 45%; $p < 0.001$. Maximal walking speed: (i) Preoperative, 94 cm/s; at 1 year, 124 cm/s (ii) Preoperative, 94 cm/s; at 1 year, 109 cm/s Preoperative, p , not significant; at 1 year, $p < 0.05$ twice as many in (ii) required ambulatory device compared with (i). Quantitative Gait Analysis: Preoperative, no significant differences between groups, but (ii) consistently better results; at + 1 year, (i) had better results in all variables. No revisions reported. | ; |
| Onsten & Carlsson, 1994 Sweden) | RCT; cemented (i) vs. porous- coated (ii) (i) Charnley (ii) Harris- Galante type I | Not specified General hospital Supine with transtrochanteric incision | (i) 30 in 30 patients (ii) 30 in 30 patients Follow-up 2 years (i) 27 patients (ii) 30 patients | Age range 40–70 years (i) mean 63 years (ii) mean 62 years | Harris Pain Score: (i) mean 42; (ii) mean 42. Harris Hip Score: (i) mean 91; (ii) mean 93. Migration/rotation: No overall differences between groups at 2 year Number of sockets displaying significant movement at 2 years: (i) 15/27 (55.5%); (ii) 28/30 (93%); p. 0.001. No revisions necessary by 2 years. | C s. |
| Dnsten, et <i>al.,</i> 1994 'Sweden) | RCT; hybrid (i) vs. cemented (ii) Charnley stem plus (i) Harris- Galante Type I cup or (ii) Charnley cup | Three MDs General hospital Lateral transtrochanteric | 58 in 29 patients Follow-up 27 months (range, 23–49 months) 42 in 21 patients | Mean age 69 years (range, 41–76) Sex Primary osteoarthritis Weight | Charnley Score for both cup types: pain: mean 6 (4–6); walking: mean 6 (3–6); range of motion: mean 5 (2–6). Maximum migration: (i) 1.7 mm; (ii) 2.1 mm. Maximum rotation: (i) 2.2 degrees; (ii) 2.0 degrees; $p = ?$ (5 Charnley and 3 Harris-Galante cups did not move). Mean values of absolute migration did not differ between groups (p , 0.06–0.98). Mean values of absolute rotation for the cups around: transverse axis: (i) 0.7; (ii) 0.4; p , 0.008 sagittal axis: (i) 0.6; (ii) 0.4; p , 0.08. | |
| Reigstad, <i>et al.,</i> 1986 Norway) | RCT; cemented vs. resurfacing (i) Müller (ii) ICLH double-cap | 13 surgeons, grades not specified Specialist hospital 14 ICLH – posterior-anterior; 135 ICLH and all Müller – anterolateral | 313 in 231 patients (i) 155 (ii) 158 Mean follow-up 48.5 months (range 27–75) Immediately postoperation, 304 (231 patients) – (i) 155; (ii) 149 + 2 years, 296 + 5 years, 89 | | (i) Charnley modified d'Aubigne & Postel: (ii) Charnley modified d'Aubigne & Postel: +5 years, 5.81 (ii) preoperative, 1.65; +2 years, 5.73°; +5 years, 5.53. Walking: (i) preoperative, 1.70; +2 years, 5.82; +5 years, 5.80 (ii) preoperative, 1.74; +2 years, 5.60°°; +5 years, 5.50. Function: (i) preoperative, 6.82; +2 years, 16.41; +5 years, 16.41 (ii) prooperative, 6.74; +2 years, 15.85°°; +5 years, 14.97 [#] ; *(i) vs. (ii): p , 0.001; **(i) vs. (ii): $p < 0.001$; #(i) vs. (ii) p , 0.014. Migration/subsidence: (i) cup: no migration; stem: 1 subsided 8 mm (ii) cup: no migration (except in 3 revised); stem: no subsidence in those not revised. Revision/loosening: (i) no revisions, 1 stem asymptomatically loose (ii) 13 (8.7%) revised [(i) vs. (ii): $p < 0.001$], 12 loose (12 stem, 8 cup). | с |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results Ratio |
|---|--|---|---|--|---|
| Søballe, et al., 1993 (Denmark) | RCT; press-fit (i) vs. HA- coated (ii) Biometric with (i) Ti-alloy coating (ii) HA coating | One surgeon, grade not specified Teaching hospital Posterolateral | 28 in 27 patients Follow-up at I year: clinical, 26 in 26 patients; roentgen stereographic analysis, 15 in 15 patients | Mean age (range) (i) 58.6 years (50–68) (ii) 56.8 years (48–63) Weight Charnley class | Harris Hip Score: C Preoperative, (i) mean 48 (SEM 2.1); (ii) mean 56 (SEM 3.7); At I year, (i) 87 (SEM 3.9); (ii) 98 (SEM 0.8) p,? Pain (Visual Analogue Scores): At rest: (mean (SEM)) (i) Preoperative, 5.9 (0.8); at I year, 2.0 (0.9) (ii) Preoperative, 5 (0.7); at I year, 0.42 (0.35) p, not significant. In function: (mean (SEM)) (i) Preoperative, 7.5 (0.67); at I year, 2.11 (0.8) (ii) Preoperative, 7.5 (0.67); at I year, 0.64 (0.35) p, not significant. Maximal total point motion (mm) or migration: (i) Mean 1.7 (SEM 0.8) (n = 8) (ii) Mean 1.7 (SEM 0.4) (n = 7) p < 0.05. Maximum subsidence in both groups – 0.2 mm. Calcar resorption – present equally in both. |
| Thanner, et al., 1995 (Sweden) Unusual | RCT: cemented Spectron EF with (i)'Palacos' cement (ii)'Boneloc' cement | Grade of surgeon not specified General hospital Transgluteal lateral | 30 in 30 patients Follow-up at 1 year 29 in 29 patients | Mean age 71 years (range, 63–76) Sex Diagnosis | Harris Hip Score – median (range): C (i) Preoperative, 51 (24–70); at I year, 90 (56–97) (ii) Preoperative, 45 (22–61); at I year, 93 (65–99); <i>p</i> , not significant. Harris Pain Score – median (range): (i) Preoperative, 20 (10–30); at I year, 40 (20–44) (ii) Preoperative, 20 (10–20); at I year, 40 (30–44) <i>p</i> , not significant. Pain Visual Analogue Scale (mm) – median (range): (i) Preoperative, 67 (50–99); at I year, 6 (0–50) (ii) Preoperative, 66 (25–100); at I year, 3 (0–37) <i>p</i> , not significant. Harris scores and Visual Analogue Scale pre- vs. postoperative: <i>p</i> , 0.0004–0.002. Migration/subsidence: (i) Cup: small lateral migration (no value); stem: 1/16 (6.25%) subsided by 0.18 mm (ii) Cup: migrated medially and proximally (no values); stem: 6/13 (46%) subsided by 0.22–1.0 mm; Stem: (i) vs. (ii) for all observations 6 weeks–12 months: <i>p</i> , 0.005. Radiolucent lines: Cup: (i) average 11% (0–47); (ii) average 30% (0–50) of acetabular cup circumference involved (<i>p</i> , 0.04); Stem (increased relative cement-cortical bone contact): (i) median 41% (9–59); (ii) median 50% (33–65); <i>p</i> , 0.03. No revisions or loosening. |
| Wykman, et al., 1991 (Sweden) (Previous reports: Wykman & Goldie, 1984; 1988) | RCT; cemented (i) vs. press-fit (ii) (i) Charnley (ii) Honnart Patel- Garches | "Experienced surgeons" General hospital? (i) Lateral with trochanteric osteotomy (ii) Posterolateral without trochanteric osteotomy | (i) 90 hips in 75 patients(?) (ii) 90 hips in 75 patients(?) Follow-up 3–5 years (i) 68 patients (ii) 70 patients | Mean age (range) (i) 67.4 years (48-82) (ii) 64.8 years (29-82) Sex Weight Diagnosis | Harris Hip Score (medians): C (i) Preoperative, 37.3; 3–5 years, 95.3; 54 patients (79%) good/excellent; (ii) Preoperative, 38.1; 3–5 years, 88.7; 48 patients (70%) good/excellent; p, not significant. Harris Pain Score (mean): (i) Preoperative, 13.5; 3–5 years, 96% patients slight or no pain (ii) Preoperative, 14.7; 3–5 years, 86% patients slight or no pain; p, not significant. Mid-thigh pain: (i) none; (ii) 6 months, 46/72 (64%) had pain; > 3 years, 18/46 still in pain, all have been/will be revised. Calcar resorption > 2 mm: (i) 38%; (ii) 58%; p, ? Migration/subsidence: (i) cup: 59% had radiolucent zone > 2 mm between bone and cement; stem: 16% subsided > 1 mm, 5% > 4 mm (radiolucent zone > 2 mm = 16% between bone and cement); (ii) cup: 67% had non-continuous radiolucent zone between implant and bone, 9% > 2 mm; stem: 66% subsided > 1 mm, 33% > 4 mm (all had non-continuous radiolucent zone between stem and bone). "Failure events", 22 patients (15%): (i) 8 (11%), 5 due to loosening; (ii) 14 (19%), all due to loosening. Survival analysis (at 5–6 years approximately): (i) 88%; (ii) 82%. |

DATA TABLE 1 contd RCTs included in the review

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
|--|--|--|---|--|--|-------|
| Abrahams & Crothers, 1992 (USA) | Prospective Omnifit-HA (i) Press-fit (ii) Hydroxapatite- coated | Not specified Teaching and general hospital Not specified | 98 in 89 patients Follow-up 1 year (i) 35 in 31 patients (ii) 63 in 58 patients | (i) 56 years (22–75) (ii) 53 years (21–73) Sex Diagnosis | Radiolucent line formation: (i) More frequent proximal line formation: (i) 20-25.7% vs. (ii) $3.2\%; p < 0.02$ (ii) More frequent distal line formation: (ii) 74.3-82.9% vs. (i) 40-42.9%; $p < 0.001$. Heterotopic bone formation: (i) No formation 39.4%; (ii) No formation, 58.%; p, not significant. Calcar resorption (% of cases): (i) 58.8%; (ii) 5.7%; p , not significant. Stem subsidence (% of cases): (i) 14.3%; (ii) 0%; p , not significant. Revisions: none reported. | с |
| Ahnfelt, et al., 1990 (Sweden) | Retrospective (i) Christiansen (ii) Charnley (iii) Charnley- Müller (v) Charnley- Müller, curved (vii) Müller, curved (viii) Wägner (ix) Stanmore (x) Müller, straight (xi) CAD (xii) Exeter (xiii) Richards II (xiv) McKee- Arden (xv) Lubinus SP plus more (not stated) Cemented: i, ii, iii, iv, v, vi, vii, ix, x, xi, xii, xv Resurfacing: viii Unknown, prob- ably cemented: xiii, xiv | Not specified (various) Not specified (various) Not specified | Total number of reoperations, 7772; number of first reoperations, 6386; number of first revisions, 4664 Follow-up – up to 10 years, 4664 (i) 1365 (ii) 971 (iii) 483 (iv) 428 (v) 288 (vi) 250 (vii) 214 (viii) 149 (xi) 101 (x) 57 (xi) 48 (xiii) 34 (xiv) 33 (xv) 18 + others | Approx. median: women 64 years; men 66 years Sex Diagnosis | Aseptic loosening main cause of both reoperation (54%) and revision (74%). Observed survival without revision for loosening: (i) 63% at 10 years (ii) 92% at 10 years (iii) not specified (iv) 93% at 9 years (v) 85% at 10 years (vi) not specified (vii) 84% at 10 years (viii) 28% at 10 years (x) 95% at 6 years (x) 95% at 8 years (xi) 95% at 8 years (xii) 95% at 5 years (xii) 95% at 5 years (xiii) not specified (xiv) not specified (xiv) not specified (xiv) not specified (xiv) not specified (xiv) not specified (xiv) not specified. Osteo/rheumatoid arthritis: Significant increase in cup loosening in rheumatoid arthritis patients > 65 years compared with osteo- arthritis ($p = $?). Osteoarthritis: men had more loosening than women in all age groups, with the 55–64 years group having the highest risk for revision for men; women have decreasing risk of loosening with increasing age ($p < 0.001$). Rheumatoid arthritis: Hospitals: regional (secondary) hospitals had better results than university (tertiary) or community (primary) hospitals with respect to loosening rates ($p < 0.001$). | c |
| Bankston, et <i>al.</i> , 1993 (USA) | Retrospective – matched (i) T-28 (stainless steel) (ii) TR-28 (cobalt–chrome) (iii) MOSC (titanium) (cup: all-polyethylene, non-metal backed) Cementing: early technique, (i) & (ii); modern technique, (iii) Cemented | l surgeon (grade not specified) Specialist hospital Lateral with trochanteric osteotomy | Total number, 568 (i) 307 (ii) 162 (iii) 99 Follow-up: (i) 8.0 years (ii) 7.6 years (iii) 7.9 years Matched = 231 (77 in each group) | (i) 66 years (ii) 67 years (iii) 65 years Sex Weight | Linear wear rates: (i) 0.06 mm/y; (ii) 0.05 mm/y; (iii) 0.08 mm/y; p, not significant. Volumetric wear rates: (i) 34.76 mm ³ /y; (ii) 33.72 mm ³ /y; (iii) 46.14 mm ³ /y; p, not significant. Acetabular progressive radiolucencies in at least one zone: (i) 24.7%; (ii) 11.7%; (iii) 26.0%; (ii) < (i), p, 0.04; (ii) < (iii), p, 0.005. Incidence of complete: (i) 11.7%; (iii) 6.5%; (iii) 3.9%; between groups, p, not significant. Femoral osteolysis/subsidence (> 5 mm): (i) Osteolysis: 5.2%; subsidence: 20.8% (iii) Osteolysis: 5.2%; subsidence: 5.2%. Osteolysis: p, not significant. Subsidence: (iii) < (ii, p, 0.008; (iii) < (ii), p, -0.004. | C |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results Ra | ating |
|--|---|---|--|--|--|-------|
| Bankston, et al., 1995 (USA) | Retrospective (i) T-28 (cup molded, early cementing technique) (ii) Triad (cup machined, mod- ern cementing techniques) Cemented | Two surgeons, grade not specified Hospital not specified Lateral with trochanteric osteotomy | (i) 162 in 151 patients (ii) 74 in 60 patients Follow-up: (i) 6.9 years (54 patients) (ii) 6.4 years (54 patients) | (i) 67 years (ii) 65 years Sex Weight | Wear rate: (i) 0.05 mm/y, (ii) 0.12 mm/y; <i>p</i> < 0.001. C Migration/subsidence: – complete progressive radiolucencies: (i) 13.0%; (ii) 5.4%; <i>p</i> , 0.75; stem subsidence: (i) 13.6%; (ii) 4.1%; <i>p</i> , 0.03. | |
| Bertin, et al., 1985 (UK & Switzerland) | Prospective Pegged poly- ethylene pros- theses designed by surgeon concerned: (i) Morscher (ii) Ring (iii) Freeman Press-fit | By or supervised by three senior surgeons University or general hospital (i) anterolateral (ii) posterolateral (iii) anterolateral | 1878 (i) 788 (ii) 967 (iii) 123 Follow-up: 2 years (6 months- 6 years) Total, 1724 | Age range (years) 20s–90s Sex Diagnosis | No differences between results from each centre so C combined results reported. Pain: 82.3% (1431), none; 14.3% (248), mild; 2.7% (47), moderate; 0.7% (15), severe. Activity level: 86.4% (1503), normal; 10.9% (190), good; 2.1% (37), fair; 0.5% (9), poor. Range of movement: 90.8% (1579), \geq 90° flexion; 7.9% (139), 60–89°; 1.2% (20), 30–59°; 0.1% (1), 0–29°. Migration: no cup migrated more than 5 mm. Revisions/loosening: 18 (1.03%) revised; 10 due to stem loosening (2 cups revised at same time), 1 due to traumatic cup loosening. | |
| Britton, et al., 1996 (UK) | Prospective (i) Charnley (ii) Stanmore Cemented | By, or supervised by, one consultant surgeon Specialist or teaching hospital Posterior (Southern) | l 190 (i) 208; (ii) 982 Follow-up: Median 8 years (40 hips with 16 years' follow-up) 834 patients (70%) | Not specified | Revisions/loosening: 81/1190 (7%) revised, 38 due to C aseptic loosening. No significant difference in cause of failure for different implants ($p > 0.5$). Survival rate at 10 years: (i) 84% ± 6.3 for a 'revision' end-point (n = 107); 44% ± 8.7 for 'onset of slight pain' end-point; (ii) 93% ± 2.6 for a revision end-point (n = 332.5); 48% ± 4.9 for onset of slight pain end-point. Survivorship curves: similar for both (i) and (ii) up to 8 years; after this (i) significantly worse for 4/5 end-points (revision or onset of different levels of pain), p , 0.026–0.004. Cementing techniques: (ii) 1st generation, 1973–79 (n = 560) – 10-year survival without revision 91.6%; 2nd generation, 1979–86 (n = 422) – 10-year survival without revision 97.4%; p , 0.005. (i) All hips (88% pre-1977) vs. (ii) n = 280 (1973–77) – 10-year survival (no revision), (i) 79.1%, (ii) 86.3%; p , 0.07. | |
| Burkart, et al., 1993 (USA) (Some information from Bourne, et al., 1994) | Prospective (i) Mallory Head – uncemented (ii) PCA (i) Press-fit (ii) Porous | Two senior surgeons (or under their supervision) Teaching hospital Direct lateral (Hardinge) | (i) 105 (100 patients) (ii) 110 (103 patients) Follow-up: 2 years (i) 94 (89.5%) (ii) ? | (i) 65 years (40-85) (ii) 61 years (26-83) Sex Side of body Osteoarthritis | Thigh pain: C (i) 3% – 3 (patients (2 mild, 1 moderate); none required analgesic, none had pain at 1 year; (ii) 23%: 3 with severe pain (no further details, previously reported). Average Harris scores: (i) Thigh pain group: hip 88, pain 38; no thigh pain group: hip 96, pain 43; (ii) No details, previously reported. Radiographic analysis: (i) Positioning – neutral 63%, mildly valgus 10%, mildly varus 28%; fit – no patient had good metaphyseal fit, 27% had good isthmal fit; subsidence: 10 patients (11%); 8 patients, 0–6 months (6 patients 3–5 mm, 2 patients 6–8 mm); 1 patient, 6–12 months by 6–8 mm; 1 with thigh pain, 3–5 mm by 6 months; calcar changes: common in those with thigh pain (100%) and without (84%); cortical hypertrophy and cancellous hypertrophy uncommon in both subgroups. (ii) Positive correlations between thigh pain and fol- lowing features made (reported in more detail previ- ously): (a) tight diaphyseal fit through the isthmus; (b) subsidence > 2 mm; (c) periosteal cortical hypertrophy at stem tip; (d) cancellous hypertrophy at stem tip. | |

| Callaghan, et al., 1995 USA) | Retrospective (a) Effect of cup design (i) Charnley (ii) Charnley in patients < 50 years (iii) cemented IOWA (2nd generation cementing technique) (iv) Harris- Galante I cup + precoated cemented stem IOWA (v) PCA cementless (vi) hybrid Harris-Galante I with precoated | Not specified | (a) n = 897 (i) 330 (> 20 years) (ii) 89 (16-22 years) (iii) 187 (> 10 years) (iv) 130 (5 years) (v) 100 (> 7 years) (v) 61 (> 5 years) (b) n = 210 (i) ? (20 years) (ii) ? (15 years) (iii) ? (10 years) (ii) ? (7 years) (v) ? (5 years) | Not specified | (a) Effect of cup design: (i) cup revision incidence 10.6% - definitely/probably loose 12.8%; stem revision incidence 3.2% - definitely/probably loose 4.3%; (ii) cup revision incidence 13% - definitely/probably loose 37%; stem revision incidence 2.2% - definitely/probably loose 6.1%; (iii) cup loosening 24.5% (metal-backed 17%, all-polyethylene 30%); stem loosening 1.2%; (iv) no revisions or loosening; (v) cup revision incidence 4% (migration incidence 5% - includes 2 revised cases); (vi) no revisions (1 migration); (b) Wear rates: Less wear in Harris-Galante I component | С |
|--------------------------------------|---|---------------|--|---------------|--|---|
| | JowA revisions (b) Wear rates (i) Charnley 22 mm machined polyethylene (ii) Charnley 22 mm molded polyethylene (iii) all- polyethylene 28 mm cemented (iv) TiBac 28 mm metal backed cemented (v) Harris- Galante I 28 mm cementess, metal backed Cemented, hybrid, porous | | | | (28 mm head) than in other cohorts (no details); p, ? | |
| Carlsson & Gentz, 1982 Sweden) | Retrospective Revisions of: (i) Charnley (ii) Brunswik (iii) Christiansen (iv) Lubinus (v) others Cemented | Not specified | 183 Follow-up: 54 months (range, 2–158) 100 (i) 45; (ii) 38; (iii) 6; (iv) 3; (vi) 8 | Not specified | 100 revisions performed, 87 due to suspected loosening (7 had no radiolucent lines around the socket and were stable at surgery). Charnley radiographic classification (modified by author): Grade 1 – total number sockets 7; number of loose sockets 0 (0%); Grade 2 – total 31; loose 4 (13%); Grade 3 – total 28; loose 4 (14%); Grade 4 – total 34; loose 22 (65%); (or Grade 4 – total 7, loose 4 (57%); and Grade 5 – total 27, loose 18 (67%)). 12/34 (35%) sockets had obvious migration or change in position on the radiographs but were stable at surgery. | С |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|---|---|---|--|---|---|--------|
| Chmell, et <i>al.,</i> 1995 (USA) | Retrospective (i) Aufranc-Turner (ii) T-28 (iii) Osteonics nonmodular stem/ cemented cup (iv) Osteonics modular stem/ ACS modular cup (vi) Osteonics modular stem/ ACS modular cup (vi) Osteonics modular stem/ cup, Dupuy Dura- loc modular cup (i) Cemented (ii) Cemented (iii) Cemented (iv) Modular (v) Modular | Three MDs General hospital Not specified | (i) 778 (ii) 823 (iii) 329 (iv) 233 (v) 203 (v) 203 (vi) ? Follow-up: (i) Average 12 years (ii) ? (58 patients, 10–14 years) (iii) average 7.5 years? (range 5–8) (iv) 6 years (v) minimum 5 years (v) ? (i) 336 (ii) ? (subgroup 58) (iii) 329 (v) 233 (v) 125 (vi) ? | Not specified | (i) 22% rate of revision for aseptic loosening, most after 6 years; loosening due to progressive bone-cement radiolucencies. In absence of loosening, bone loss or osteolysis not seen. (ii) Stem loosening greater with 1st generation cementing techniques than 2nd but osteolysis not seen in either group unless loosening occurred. In 58 patients (follow-up 10–14 years), 3.4% cups revised for loosening, 21% had continous radiolucencies but no osteolysis apparent. (iii) 28 mm head group: revision for loosening 2.1%; average time to revision 91 months. (iv) Revision for loosening 3.0%; average time to revision 71 months. (v) 75/125 had polyethylene thickness < 6 mm; 13 revised for liner wear or fracture (average 41 months) 19 with eccentric wear, 15 with osteolysis. Remaining 50/125 had liner > 6 mm; 2 revised for liner fracture, 5 for eccentric wear, 4 were osteolytic. (vi) "Have not been associated with the catastrophic failure rate seen in the ACS cups" – no further details given. | |
| Cornell & Ranawat, 1986 (USA) Unusual | Retrospective (i) Charnley, CAD, Müller, T-28 (using early cementing techniques) (ii) Charnley, DF-80 (using modern cement- ing techniques) Cemented | Not specified Specialist hospital Posterior (38%) or trans-trochanteric (62%) | 101 in 85 patients Follow-up: (i) vs. (ii) = 5 years (i) subgroup analysis 5 years vs. 10.7 years 78 (62 patients) (i) 62 (48 patients) (ii) 16 (14 patients) | (i) 48 ± 7.6 years (ii) 48 ± 9.4 years Sex Weight Diagnosis | | C |
| Dall, et <i>al.</i> , 1993 (South Africa) Unusual | Retrospective Charnley (i) 1st generation design (ii) 2nd generation Cemented | Consultant, 97%; residents, 3% Specialist and general hospital Not specified (> 95% trochanteric osteotomy) | 1309 in 1089 patients Follow-up: (i) 8.8 years; (ii) 7.8 years 666 (555 patients) (i) 264; (ii) 402 | (i) 60.7 years (ii) 60.3 years Sex Diagnosis Charnley class | Modified d'Aubigne–Postel (grades 5–6): (i) pain 82.7%; function 73.4%; motion 75.0%; (ii) pain 83.6%; function 77.1%; motion 81.8%. p, ? (unrevised hips only; function: Charnley class C excluded). Wear (cup): (i) 1–2 mm, 15.7%; 3–4 mm, 4.2%; (ii) 1–2 mm, 11.7%; 3–4 mm, 2.5%. p , ? Resorption (stem): (i) 1–2 mm, 3.8%; 3–4 mm, 13.3%; 5 mm+, 9.4%; (ii) 1–2 mm, 4.1%; 3–4 mm, 6.2%; 5mm+, 7.4%. p , ? Radiolucency (stem): (i) 13.2%; maximum width: 2 mm, 2.9%; 3 mm+, 3.4%. (ii) 20.4%; maximum width: 2 mm, 8.1%; 3 mm+, 5.0%; p, ? Radiolucency (cup): (i) 49.4%; maximum width: 2 mm, 8.2%; 3 mm+, 2.5%. (ii) 50.7%; maximum width: 2 mm, 5.8%; 3 mm+, 3.6%; p, ? Migration/subsidence: stem: (i) 2 mm, 5.0%; 3 mm+, 7.1%; (ii) 2 mm, 2.3%; 3 mm+, 6.8%; cup: (i) 1–2 mm, 2.5%, 3 mm+, 2.1%, p , ? Probable loosening (no revisions): (i) 9/264 (3.4%): cup 1.9%, stem 1.6%, both 0%; (ii) 27/402 (6.7%): cup 2%, stem 3.7%, both 1%. 10-year survival probability related to loosening: (i) 91.5%; (ii) 86.8%; (95% Cl, 80.9–92.8; $p < 0.0001$). Revisions: (i) 21 (8%). Loosening: cup only 1; stem only 2; both 2; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; (ii) 38 (9%). Loosening: cup only 2; stem only 18; both 9%; | C Q |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
|--|--|---|--|---|--|-------|
| Duck & Mylod, 1992 (USA) | Retrospective Various types of prosthesis used | Not specified Teaching hospital Anterolateral 41%; | 66 in 55 patients Follow-up: 36 months | 60.3 years (33–76) Sex | Occurrence of heterotopic bone formation (HBF): Total hip: cemented, 15/22 (68%); noncemented, 10/17 (59%). | с |
| | but a 'significant percentage' were: (i) AML Porcoat (ii) Dual-Lock | anterolateral 41%; posterolateral 38%; anterior 14%; trans- trochanteric 7% | (i) 39 (ii) 18 (iii) 9 | Diagnosis Side of body | Hemi-arthroplasty: cemented, 9/13 (69%); noncemented, 2/5 (40%). Resurfacing: 5/9 (56%); (11/17 (65%) revision cases | |
| | (iii) TARA & Indian Conservative Hip | a | . , | | had HBF). No significant correlation between type of | |
| | (i) Porous-coated (ii) Cemented (iii) Resurfacing | | | procedure and % bone formation. Pain and HBF, no correlation; range of movement and HBF, trend of decreasing range of motion with increasing HBF. | | |
| ibramzadeh, t <i>al.</i> , 1994 USA) | Retrospective (i) Charnley stem (ii) STH stem plus unknown cup Cemented | One MD Teaching hospital (i) Lateral with trochanteric osteotomy (ii) Posterior without trochanteric osteotomy | 857 in 720 patients Follow-up: 9 years (1–21) 836 (i) 413 (ii) 423 | < 50 years (i) n = 67 (ii) n = 61 > 50 years (i) n = 346 (ii) n = 362 Sex Weight Diagnosis | Best results if: (a) > 2 mm and < 5 mm proximal medial thickness of cement mantle; (b) < 2 mm proximal medial thickness of cancellous bone; (c) stem filled more than half of distal part of medullary canal; (d) stem in neutral orientation. Worst results if: (a) cement mantle > 10 mm thick; (b) > 2 mm of proximal medial thickness of cancellous bone; (c) stem filled half or less of medullary canal; (d) varus orientation. | С |
| Espehaug, et al., 1995 Norway) | Retrospective Cup/stem (i) Charnley/ Charnley (ii) Exeter/Exeter (polished) (iii) Titan/Titan (iv) Spectron/ITH (v) Elite/Charnley (vi) Spectron/ Lubinus SP (vii) Biomet/ Biomet (viii) Spectron/ Biofit (ix) Lubinus SP/ Lubinus SP (x) Müller type/ Müller type Cemented | Not specified Various hospitals Not specified | Total number 18,848; after restrictions, 12,179 in 11,169 patients) Follow-up: mean 3.2 years, maximum 6.4 years 12,179 (i) 6654 (ii) 1665 (iii) 1333 (iv) 1034 (v) 507 (6) 302 (vii) 247 (viii) 152 (ix) 129 (x) 116 | < 65 years, 15% 65–74 years 49% > 74 years 36% Sex | Survival analysis: 5-year failure rate (overall 2.5%) (i) Charnley/Charnley, 2.86% (ii) Exeter/Exeter, 2.15% (iii) Titan/Titan, 1.23% (iv) Spectron/ITH, 0.85% (v) Elite/Charnley, 9.84% (vi) Spectron/Lubinus SP, 4.96% (vii) Biomet/Biomet, 1.25% (viii) Spectron/Biofit, no revisions (ix) Lubinus SP/Lubinus SP, no revisions (ix) Breised (1.7%), 63% due to loosening (ii) 23 revised (1.4%), 48% due to loosening (iii) 115 revised (0.9%), 83% due to loosening (iv) 4 revised (0.4%), 25% due to loosening (iv) 12 revised (2.4), 25% due to loosening. Other combinations, 18 revised (1.9%), 100% loose. Bilateral vs. unilateral. Results of survival analysis similar in both. | с |
| Freeman & Plante- Bordeneuve, 1994 UK) | Prospective 'Specially designed' Parts I & 2 (i) Press-fit (ii) Cemented Part 3 (i) Press-fit (iii) Cement (iii) Press-fit with proximal longi- tudinal ridges (iv) HA-coated | Not specified Teaching Not specified | (i) 125 in 117 patients (ii) 81 in 77 patients (iii) ? (iv) ? Follow-up: (i) & (ii), > 5 years (iii) & (iv), 2 years (i) At 2 years, 100 in 93 patients; at > 5 years, 89 in 81 patients (ii) At 2 years, 55 in 54 patients (ii) At 2 years, 38 in 37 patients (iii) At 2 years, 34 in 38 patients (iv) At 2 years, 34 in 34 patients | (i) 54 years (22–84) (ii) 67 years (48–83) At 2 years: (iii) 51 years (27–73) (iv) 52 years (33–76) Sex Diagnosis Side of body | Loosening (thigh pain needing analgesic or revision): (i) 22/89 (24.7%); (ii) 3/38 (7.9%); p, ? Migration: Rate of migration at > 5 year follow-up – (i) 0.78 mm/y; (ii) 0.27 mm/y; $p < 0.0001$; (i) loose hips 1.5 mm/y; stable hips 0.6 mm/y; p < 0.0001; (ii) loose hips 3.4 mm/y; stable hips 0.2 mm/y; p, ? Amount of migration at 2-year follow-up – (i) all (n = 100) 1.85 mm; no pain (n = 80) 1.45 mm; (iii) all (n = 55) 0.55 mm; no pain (n = 52) 0.38 mm; (iii) all (n = 55) 0.55 mm; no pain (n = 36) 1.3 mm; (iv) all (n = 34) 0.4 mm; no pain (n = 34) 0.4 mm; p, ? 'Migration test': Migration test': Migration tat of 1.2 mm/y had 78% sensitivity and 86 specificity for distinguishing hips which would fail. (Group 4 at 4 years: no hips termed loose or revised; techniques used in groups 1 and 3 were discontinued. | % |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|--|--|--|---|--|--|---------|
| Goetz, et <i>al.,</i> 1994 (USA) | Retrospective – matched Cup: Harris- Galante (cementless) Stem: (i) Harris-Galante (cementless) (size: 28 mm (23), 26 mm (16), 22 mm (2)) (ii) Precoat (cemented) (size: 32 mm (2), 28 mm (9), 26 mm (28), 22 mm (2)) (i) Porous-coated (ii) Hybrid | One senior surgeon Teaching/ general hospital Not specified, but same for all patients) | Total 255: (i) 88 (ii) 167 Selected 82 in 74 patients Follow-up (range): (i) 74 months (43–100) (ii) 72 months (48–94) (i) 41 (ii) 41 | (i) 57 years (40–69) (ii) 61 years (40–71) Weight Diagnosis | Harris Hip Score: Preoperative: (i) 49 (33–66); (ii) 53 (32–70); p, ?; Latest follow-up: (i) 89 (40–100); (ii)97 (84–100); p < 0.002. Osteolysis: (i) stem: 12/41 (29%) (5 loose); (ii) stem: 0; p < 0.0002. No relationship between size of femoral head and osteolysis. Revisions/loosening: (i) stem: 5 (12%) revised (4 due to loosening); 8 subsided/migrated; cup: no migration/revisions. (ii) stem: no revisions ($p < 0.02$), all radiographically stable, no radiolucent lines; cup: no migration/ revisions. | С |
| Hamada, et <i>al.,</i> 1993 (Japan) | Retrospective (i) Model Y (ii) Model Y2 Press-fit | Not specified Teaching hospital Not specified | 71 in 71 patients Average follow-up (maximum): (i) 4 years 7 months (6 years 9 months) (ii) 1 year 8 months (2 years 9 months) (i) 26 (ii) 25 | (i)65 years (43-81) (ii)61 years (40-81) Sex Diagnosis | Extent of press-fit (contact ratio) I year postoperatively: (i) Excellent 7; Good 8; Fair 11; (ii) Excellent 23; Good 2; Fair 0; p, ? Thigh pain: (i) 11/26 (42%) patients with pain for 1–6 months and 6–24 months postoperatively; (ii) 2/25 (8%) patients with pain for 1–3 months and 1–8 months postoperatively; p, ? | C |
| Havelin, et <i>al.,</i> 1994 (Norway) | Retrospective (i) Cemented (27 cup and 22 stem types) (ii) Cementless (19 cup and 18 stem types including: smooth-surfaced, porous- and HA-coated) Cemented Press-fit Porous-coated HA-coated | Various grades of surgeon Various hospitals Not specified | 15,335 (i) 14,009 (ii) 1326 Follow-up: 0–5.4 years 15,335 | (i) mean 71 years (ii) mean 59 years Uncemented: < 65 years 31% > 65 years 3% Sex | Aseptic loosening (cumulative survival until revision due to loosening) caused 68% of 263 failures. (i) Cup 99.4%, stem 98.3%, after 4.5 years (ii) Cup 98.4%, stem 96.1% after 4.5 years; 2.3 times more likely than (i) to need revision because of loosening. Revisions after 4.5 years: (i) All hips 2.7%; < 65 years 3.3%; women 1.9%; men 4.5%; (ii) All hips 6.5%; < 65 years 7.9%; women 6.3%; men 6.8%. Risk of revision: Uncemented hips at 2.0 times higher risk than cemented when adjusted for sex and age; increase in risk for patients aged < 60 years with uncemented hips is 2.9 compared with 2.4 and 1.2 in those aged 60–64 and > 65 years, respectively. | |
| Havelin, et <i>al.</i> , 1995 (Norway) | Retrospective Stem: (i) Biofit (iii) Corail (iii) Femora (iv) Harris- Galante (v) LMT (v) RM- prosthesis (vii) Profile (viii) Zweymuller Various | Not specified – various Various hospitals Not specified | 2907 in 2421 patients Follow-up range: 0–5.4 years 2907 | Range 15–87 years Mean range 48–63 years Sex Diagnosis | Revision rates for aseptic loosening (overall 4.5%) and cumulative survival after 4.5 years: (i) 18.6% & 81.4%; (ii) < 1% & 99.5%; (iii) 13.6% & 86.4%; (iv) 3.6% & 96.2%; (v) < 1% & 99.5%; (vi) 5.6% & 94.4%; (vii) 0% & -; (viii) < 1% & 99.1%. | С |
| | | | | | | continu |

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| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
|---|---|---|--|---|---|-------|
| Hearn, et <i>al.,</i> 1995 (USA) | Retrospective (i) Cemented Charnley, Dual Lock, Pennsyl- vania Total Hip (ii) Uncemented Trilock, Taperloc (i) Cemented (ii) Porous | Not specified | 72 in 36 patients Most recent visit: (i) 8.1 years (2.7–18.2) (ii) 3.0 years (2.0–5.9) At same interval: (i) 3.6 (ii) 3.0 60 in 30 patients | (i) 59 years (21–76) (ii) 63 years (25–82) Sex Diagnosis | Charnley Scores: (i) Preoperative – pain 3.1; motion 3.0; function 2.5; most recent – pain 5.6; motion 5.5; function 5.3; same interval – pain 5.7; motion 5.1; function 5.3. (ii) Preoperative – pain 2.5; motion 3.6; function 2.5; most recent/same interval: pain 5.6; motion 5.6; function 5.3. Preoperative pain (i) vs. (ii), p, 0.002. Range of movement: same interval (i) vs. (ii), p, 0.002. Harris Hip Scores (most recent visit, 19 patients only): (i) 91.6 (75.5–99.7); (ii) 91.3 (55.7–99.7); p, not significant. Patient preference: cementless 39%; cemented 22%; no preference 39%. No migration or subsidence noted. Loosening: (i) one stem probably loose; (ii) none. Revisions: none reported. | С |
| Hedlundh & Fredin, 1995 (Sweden) Unusual | Retrospective – matched Charnley (i) Dislocated (ii) Not dislocated Cemented | Not specified Teaching hospital Trans-trochanteric | Total 1838 (i) 60 (ii) 120 Follow-up period not specified (i) 60 (ii) 118 | Total group median 70 years (22–94) (i) median 71 years (43–89) (ii) median 71 years (52–85) Sex Diagnosis Side of body | Mortality: (i) 32/60 (53%); (ii) 29/118 (24.5%); p < 0.001; death risk same for single and recurrent dislocations. Median age at death (range): (i) 77 years (56–90); (ii) 77 years (59–91); p, not significant. Logistic regression: gender, length, weight, obesity, previous contralateral hip surgery and previous arthrotomy of ipsilateral knee had no influence on dislocation rate. Alcoholism (in men only): (i) 10/20 (50%); (ii) 7/38 (18%); p, 0.01. | C |
| Hernandez, et al., 1994 (USA) | Retrospective Cup: Universal cup design Stem: Bimetric (i) cemented (ii) uncemented (ii) Hybrid (ii) Porous- coated | Not specified Specialist hospital Posterior without trochanteric osteotomy | 231 in 203 patients Follow-up: Minimum 3 years; maximum 5 years (i) 97 (ii) 134 Also matched: (i) 66 in 58 patients (ii) 65 in 58 patients | Age not specified Sex matched but not specified Weight matched but not specified Diagnosis | Mean linear wear (range): (i) all cups: 0.42 mm (0–2.75); matched 0.47 mm (0–2.75); (ii) all cups: 0.73 mm (0–4.21); matched 0.72 mm (0–4.21); p < 0.04 for both. Mean linear wear rate (range): (i) all: 0.14 mm/y (0–0.92); matched: 0.15 mm/y (0–0.92); (ii) all and matched: 0.22 mm/y (0–1.41); ($p < 0.05$). Radiolucent lines: (i) 7 cup side; 1 stem side (1 stem subsided); (ii) 6 cup side; 5 stem side (no subsidence). | C |
| Hodgkinson, et al., 1993 (UK) | Retrospective Charnley (i) flanged (ii) unflanged Cemented | Not specified but same group for each cohort Specialist hospital Standard Charnley technique | 350 Follow-up: Maximum 9–11 years 313 in total Clinical data: (i) 150 (ii) 152 | (i) 60.6 years (ii) 58.2 years (pre-operation or follow-up?) Sex Weight Diagnosis | Mean pain score: (i) 3.11; (ii) 3.13; p, not significant. Mean function score: (i) 2.81; (ii) 2.76; p, not significant. Mean movement score: (i) 2.58; (ii) 2.65; p, not significant. Radiolucency: Grade 0 (none): (i) 43%; (ii) 30%; Grade 1: (i) 39%; (ii) 45%; Grade 2 and above; radiographic loosening; progression of radiolucency almost identical for both groups. Revisions: 15/350 (4.3%) revised (11 within 10 years, 4 at or after 10 years), 9 with radiographic loosening. | С |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|--|--|---|--|--|---|----------|
| Hoffman, et al., 1994 (New Zealand) Horikoshi, et al., 1994 (USA) | Retrospective (i) Charnley (74.4%) (ii) Harris- Galante (9.0%) (iii) Müller (7.9%) (iv) PCA (v) Autophor (vi) Brunswick (vii) Wrightington (vii) Wrightington (vii) McKee (ix) Indiana Cemented (i) (iii) (vi-viii) Porous (ii) (iv) Ceramic (v) Resurfacing (ix) Retrospective (i) Uncemented stem (as below) | Six surgeons, grades not specified General and private hospital Not specified Not specified Teaching hospital | 1166 in 974 patients (i) 867; (ii) 105; (iii) 92; (iv) 38; (v) 35; (vi) 14; (vii) 5; (viii) 5; (ix) 2 Maximum possible follow-up 20 years 1156 (99.1%) 36 in 36 patients (i) 18 (ii) 18 | Average (at operation) 66.2 years (SD 10.1) Sex Side of body Diagnosis (i) 65 years (28–90) (ii) 73 years (c4 96) | Multivariate regression analysis: four significant factors for survival: sex, age, surgeon, hospital. Revisions/loosening: (i) 72 failures (6 loose); (annual failure rate 1.78%; 15-year survival rate 73%); (ii) no failures; (iii) 26 failures (23 loose); (annual failure rate 6.93%; 11-year survival rate 63%); (iv) no failures (v) failure rate in first 3 years 15%. (Remainder not given as numbers too small) Radiolucency: (i) complete radiolucent line > 2 mm, 5/18 (28%); partial radiolucency, 12 (66%); 1 migrating prosthesis (49%). | C |
| | + uncemented cup: 4 Harris-Galante porous 4 Richards porous 4 BlAS 2 Osteonic 2 Macrofit 1 Intermedic 1 PCA (ii) Cemented stem (as below) + cemented cup: 5 T-28 4 Aufranc-Turner 3 Harris Design- 2 2 Harris-Galante Porous-1 1 Biomet 1 Charnley 1 Müller 1 Buck 32 Uncemented vs. cemented | Not specified | Follow-up (range): (i) 4.9 years (1–16) (ii) 10.3 years (2–20) p < 0.02 (i) 18 (ii) 18 | (64–86) Sex Diagnosis | (6%); (ii) complete radiolucent line > 2 mm, 12/18 (67%); partial radiolucency, 4 (22%); 2 migrating prostheses (11%); p,? Intraoperative examination: all components loose; all surrounded by fibrous tissue membrane 2–15 mm thick. | |
| Hozack, et <i>al.,</i> 1993 USA) | Prospective, controlled Stem: (i) Dual-Lock (80% metal- backed) (ii) Trilock (98% metal-backed) Cup: cemented (i) Cemented (i) Porous- coated | Not specified Teaching hospital Not specified | (i) 71 in 66 patients (ii) 70 in 61 patients Follow-up (range): (i) 4.3 years (2–6.5) (ii) 4.1 years (2–6) (i) 71? (ii) 70? | (i) 64 years (32–82) (ii) 52 years (25–72) Sex Weight Charnley class Diagnosis | Charnley Scores (preoperative): pain – (i) 3.1; (ii) 3.0; p. not significant; function – (i) 2.6; (ii) 2.6; p. not significant; motion – (i) 3.1; (ii) 3.1; p. not significant. Charnley Scores (postoperative): pain – (i) 5.6; (ii) 5.7; p. not significant; function – (i) 5.1 (ii) 5.6; p. not significant. Cup migration > 5 mm (all cemented): (i) 2 (7.3%); (ii) 4 (6%); p. not significant. Definite/probable loosening of stem: (i) 3 (4%); (ii) 3 (4%). Revisions: (i) 1 (1.4%) for loosening; (ii) none. | C |
| | | | | | | continue |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|---|--|--|---|---|---|--------|
| Hozack, et <i>al.,</i> 1994 (USA) | (i) Prospective (ii) Retrospective (ii) Stem: Taperloc, Cup: cemented or uncemented (ii) (a) As for (i) vs. (b) cemented components (i) Porous-coated (ii) Porous-coated vs. cemented | (i), (ii)(a) By, or supervised by, one senior surgeon (ii)(b) ? Teaching hospital (i), (ii)(a) Either direct lateral or trans-trochanteric (ii)(b) ? | (i) (ii) (a) 100 (ii) (b) ? Follow-up (range): (i) 3.8 years (2-6) (ii) (a) 3.8 years (2-6) (ii) (b) 3.5 years (2-6) (i) 94 (ii) (a) 52 (ii) (b) 52 | (i) 56 years (25-79) (ii)(a) 62 years (48-79) (ii)(b) 67 years (48-79) Sex Weight Diagnosis | (i) Charnley Scores, pre- vs. postoperative (range): pain, 3.0 (2–5) vs. 5.5 (2–6); function, 2.8 (2–6) vs. 5.4 (2–6); range of motion, 3.1 vs. 5.6; p,? (i) Limp: 89% no limp; 11% mild/moderate limp. (i) Revisions/loosening: no revisions, all stems stable. (ii) Charnley Scores (pre- vs. post-operative): pain, (a) 3.0 (b) 3.0, vs. (a) 5.6 (b) 5.7; function, (a) 2.7 (b) 2.9, vs. (a) 5.5, (b) 5.5; motion, (a) 3.1, (b) 3.2, vs. (a) 5.5, (b) 5.6; (for all (a) vs. (b) comparisons, p, not significant). (ii) Limp: (a) no limp 88%; mild/moderate limp 12%; (b) no limp 90%; mild/moderate limp 10%. (ii) Revision/loosening: (a) and (b), no revisions, all components stable. | с |
| Huracek & Spirig, 1994 (Switzerland) | Retrospective, matched Mecron cementless (i) with HA-coating (ii) without HA-coating (i) HA-coating (ii) Press-fit | One surgeon, grade not specified General hospital Lateral | 127 in 121 patients Follow-up: 4.1 years (i) 40 (ii) 40 | 71.1 years Sex All primary osteoarthritis | Harris Hip Scores (modified): (i) Pre- vs. postoperative, 48 vs. 78; (ii) Pre- vs. postoperative, 45 vs. 74; p, not significant. Pain: no pain – (i) 59.3%; (ii) 22.5%; $p < 0.0016$. Migration/subsidence: (i) cup, no migration; stem, 3 (7.5%) subsided/migrated; (ii) cup, 13 (32.5%) migrated by 5 mm or more; stem, 12 (30%) subsided/migrated. Revisions or loosening: 0/80. | с |
| Hwang & Park, 1995 (Republic of Korea) | Prospective (i) AML (ii) PCA (iii) Harris- Galante Porous Porous-coated | One surgeon Teaching hospital Direct lateral (44% PCA) Posterior (56% PCA, 100% AML, Harris-Galante Porous) | 289 Follow-up (range): (i) 5.2 years (2.1–8.5) (ii) 4.7 years (3.1–8.0) (iii) 3.8 years (2.0–6.9) 270 in 214 patients (i) 90 (+5 years, 71) (ii) 117 (+5 years, 90) (iii) 63 (+5 years, 42) | (i) 51.2 years (20-79) (ii) 46.2 years (24-79) (iii) 46.3 years (25-86) Sex Diagnosis | Harris Hip Scores: (i) preoperative, 45; latest follow-up, 93; excellent, 71% (ii) preoperative, 41; latest follow-up, 91; excellent, 76%; (iii) preoperative, 44; latest follow-up, 91; excellent, 69%; p, ? Thigh pain (at 5 years): (i) 17%; (ii) 21%; (iii) 19%; $p, ?$ Stem orientation: (i) neutral 90%; varus 4%; valgus 6%; (iii) neutral 87%; varus 9%; valgus 4%; (iii) neutral 94%; varus 9%; valgus 4%; (iii) neutral 94%; varus 5%; valgus 1%; p, ? Osteolysis of the neck: (i) 8%; (ii) 15%; (iii) 10%; $p, ?$ Loss of proximal bone density: (i) 7%; (ii) 20%; (iii) 13%; $p, ?$ Heterotopic bone formation (mild or moderate): (i) 15.6%; (ii) 15.4%; (iii) 9.5%; $p, ?$ Stem subsidence – 2.1 mm (0–8), > 3 mm 10%; migration – present at 3 years 10%, progressive 3.3%; (ii) subsidence – 1.9 mm (0–6), > 3 mm 12.7%; migration – present at 3 years 12.7%, progressive 4.8% Cup migration (present at 1 year): (i) 3.3%; (ii) 4.3%; (iii) 4.8%; no progressive migration. Average wear rate (range) of polyethylene liner: (i) 0.7 mm/y (0.5–3.1); (ii) 0.6 mm/y (0.4–2.8); (iii) 0.8 mm/y (0.6–2.8); $p, ?$ | |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratir |
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| Jacobsson, et al., 1990 (Sweden) (Previous report: Djerf & Walstrom, 1986) | Prospective (i) McKee-Farrar (ii) Charnley Cemented | Eight surgeons, various grades Teaching hospital (i) dorso-lateral (as decribed by McKee and Farrar) (ii) lateral with trochanteric osteotomy (as described by Charnley) | 177 in 169 patients) (i) 107 (ii) 70 Follow-up (range): (i) 11.9 years (10.7–13.5) (ii) 11.0 years (10.1–12.8) (i) 55 (ii) 41 (55 died, 22 revised, 4 lost to follow-up) | 66.9 ± 8.1 years Sex Weight Diagnosis | Walking ability (data given for total group only): Distance: preoperative average 200 m, +2 years 2000 m (stayed constant at subsequent follow-ups). Speed: preoperative average 0.5 m/s, +1 year 1.0 m/s. +11.5 years 0.7 m/s. No requirement for aids: preoperative 3%; +5 years 45%; +11.5 years 23.3% and 50% did not use them regularly. Harris Hip Score: (i) mean 74.8 ± 17.3 (44% good/excellent); (ii) mean 72.9 ± 19.6 (51% good/excellent); (ii) mean 72.9 ± 19.6 (51% good/excellent); p, ? Pain score – no or occasional pain: (i) 76%; (ii) 69%; p, ? Revisions: 22/118 (18.6%) – (i) 16; (ii) 6; (number caused by loosening not given). Loosening: 30/93 (32.2%) radiographic loosening; (i) 14–8 stems, 2 cups, 4 both; (ii) 16–10 stems, 2 cups, 4 both. Survivorship analysis: Mean annual rate of re-operation – (i) 1.61%; (ii) 0.91%; p, not significant. Cumulative numbers of survivors – (i) 82.2%; (ii) 89.5%; p, not significant. Wire vs. cable: | |
| Kelley & Johnstone, 1992 (USA) Unusual | Retrospective Stem: Charnley or Iowa Cup: 22 mm Charnley, 28 mm polyethylene, 28 mm metal- backed with: (i) Stainless steel monofilament wire (ii) Cobalt– chrome cable Cemented | One surgeon, grade not specified Not specified Transtrochanteric with trochanteric osteotomy | Total 796 patients Number with surgical approach required, 643 Follow-up: (i) 6 years 1 month (ii) 5 years 11 months (i) 162 patients (ii) 160 patients | (i) 67 years (ii) 65 years Sex Diagnosis | Wire vs. cable: Trochanteric union rates: wire 75%; cable 79%. Non-union rates: wire 13%; cable 8%; p, 0.36. Breakage (all three wires/cables): wire 43%; cable 12%; $p < 0.001$. Migration of wire/cable debris or fragments: Wire: to cup notch area 8%, $< 2 \text{ cm } 26\%$; Cable: to cup notch area 16%, $< 2 \text{ cm } 26\%$; Cable: to cup notch area 16%, $< 2 \text{ cm } 26\%$; Cable: to cup notch area 16%, $< 2 \text{ cm } 26\%$; Bone destruction: (i) 9%; (ii) 29%; $p < 0.001$. Rates of loosening (according to prosthesis type): Charnley: total 3/70 (4.3%); wire 2/42 (4.7%); cable 1/28 (3.6%). 28 polyethylene: total 24/68 (35.3%); wire 9/30 (30%); cable 15/38 (39.5%). 28 metal-backed: total 30/184 (16.3%); wire 9/90 (10%, cable 21/94 (22.3%). Differences in cup loosening, adjusted for type: p , 0.003 Revisions/loosening of total group (n = 643): (i) 4 revisions (2.4%), 2 for cup loosening; (ii) 10 revision (6.25%), 5 for cup loosening; (further surgery required: (i) 5; (ii) 5.) | |
| Krismer, et <i>al.,</i> 1991 (Austria) | Retrospective (i) Müller straight-stem with (a) cementless RM cup or (b) cemented Müller standard cup (ii) Müller standard-stem Cemented | Not specified Teaching hospital Not specified | Total, 1099 (i) 422 (ii) 583 After criteria applied, 503 in 452 patients Follow-up: 5.8 years (± 1.24) 425 in 383 patients (i) 263 (ii) 162 | 60.9 ± 7.4 years Sex Diagnosis | Hip pain in groups 5 and 6, d'Aubigne classification: (i) 87% patients; (ii) 80% patients; p, not significant. Subsidence: (i) 32/260 (12%) migrated > 2 mm; (ii) 17/159 (10.6%) migrated. Loosening (maximum follow-up 7–8 years): (i) 21/260 (8%) (RM cup, 12/156, 7.7%; cemented cup, 9/104, 8.7%); (ii) 19/159 (11.9%) (cemented cup). Revisions due to loosening: stems (i) 5 (1.9%); (ii) 6 (3.7%). | С |
| Krismer, et al., 1991 (Austria) | Retrospective (i) RM cup (uncoated) (ii) Müller cup (with Müller straight or standard stems) (i) Press-fit (ii) cemented | Not specified Teaching hospital Not specified | Original numbers: (i) 207; (ii) 892 After criteria applied: (i) 173 in 160 patients (ii) 309 in 292 patients Follow-up: (i) 5.3 \pm 1.1 years (ii) 6.1 \pm 1.3 years (i) 160 in 147 patients (ii) 263 in 236 patients | (i) 57.3 ± 7.2 years (ii) 62.9 ± 6.7 years Sex Diagnosis | Subjective results: Satisfied (i) 94.6%; (ii) 91.7%; p, not significant. Range of motion: Flexion: (i) 102 \pm 16.9; (ii) 93 \pm 15.3; $p < 0.001$. Gain in flexion: (i) 27 \pm 24; (ii) 20 \pm 26; p, 0.011. Migration: (i) 35/140 (25%) migrated between 2.1 and 16 mm; (ii) no migration values recorded. Revisions/loosening (after 7–8 years): (i) 12% revised, 40% loose; (ii) 4% revised; 15% loose; p,? | С |

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| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
|--|---|---|--|--|--|-------|
| Kristiansen & Steen Jensen, 1985 (Denmark) Jnusual | Retrospective, matched Stanmore (standard type, 29 mm head, small collar, 142 mm stem) Cemented | Not specified Teaching hospital Not specified | 320 in 308 patients) Follow-up (range): 36 months (4–68) (i) 33 revisions (due to loosening) (ii) 33 controls | 64 years (48–79) at primary surgery Sex Weight Diagnosis | Cortical index (range) at the calcar femoral: (i) 0.15 (0.12–0.21); (ii) 0.18 (0.13–0.27); $p < 0.01$ (i.e. calcar bone stock thin prior to surgery). Cementation technique: Insufficient packing, (i) 29/33 (88%); (ii) 13/33 (39%); p, 0.0005. Positioning of the prosthesis: valgus, (i) 8/33 (24%); (ii) 10/33 (30%); neutral, (i) 7/33 (21%); (ii) 16/33 (48%); varus, (i) 18/33 (55%); (ii) 7/33 (21%); $p < 0.0005$; varus position is related to loosening in stem. | В |
| Lehman, et <i>al.</i> , 1994 USA) Jnusual | Retrospective Stem: HS2P, Omnifit, Omniflex Cup: Dual- geometry, Peripheral Self- Locking, Mecron ring, Harris- Galante cup Various uncemented | By, or supervised by, one senior surgeon Teaching hospital Not specified | 324 in 284 patients; divided by body-mass index: (i) 20–29 normal (ii) 30–39 obese (iii) 40+ within group (ii) morbidly obese (< 20 excluded) Follow-up (range): (i) 249 months (24–89) (iii) 45 months (25–81) (i) 142 in 127 patients (ii) 60 in 55 patients (iii) 8 in 8 patients part of (iii)) | (i) 48 years (19–73) (ii) 50 years (17–67) (iii) 52 years (37–72) Sex Diagnosis Weight Body Mass Index | Clinical parameters: Pain (no/mild pain pre- vs. postoperative) – (i) 3 (2%) vs. 129 (91%); $p < 0.001$; (iii) 0 (0%) vs. 48 (92%); $p < 0.001$; (iii) 0 (0%) vs. 7 (88%); $p, 0.02$; p, not significant – (i) vs. (ii), (ii) vs (iii). Mobility (not needing support to walk, pre- vs. postoperative): (i) 73 (51%) vs. 130 (92%); $p < 0.001$; (iii) 3 (34%) vs. 44 (85%); $p < 0.001$; (iii) 3 (34%) vs. 5 (63%); $p, not significant;(postoperative (ii) vs. (iii) p < 0.05; all others,p$, not significant). Limp (no/slight limp) pre- vs. postoperative: (i) 46 (32%) vs. 131 (92%); $p < 0.001$; (iii) 7 (13%) vs. 44 (85%); $p < 0.001$; (iii) 7 (13%) vs. 44 (85%); $p < 0.001$; (iii) 2 (25%) vs. 6 (75%); $p, 0.043$ (p , not significant – (i) vs. (ii), (ii) vs. (iii)). Trendelenburg sign present (pre- vs. postoperative): (i) 63 (44%) vs. 126 (89%); $p < 0.001$; (iii) 2 (038%) vs. 47 (90%); $p < 0.001$; (iii) 2 (038%) vs. 47 (88%); $p < 0.001$; (iii) 2 (25%) vs. 7 (88%); $p < 0.001$; (iii) 2 (25%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 2 (15%) vs. 7 (88%); $p < 0.001$; (iii) 0 (13%; (ii) 13%; (iii) 2/8 (25%); p , not significant. Class IV: no patient in any group. Osteolysis of femur: (i) 13%; (ii) 13%; p , not significant ((iii) 0%). Wear of polyethylene acetabular liner: 2 mm or more: (i) 3%; (ii) 2%; p , not significant ((iii) 0%). Revisions/loosening: (i) cup, 7 (4.9%) revised (all loose) + 3 loose; stem, 9 (6.3%) revised (all loose) + 2 loose; (ii) cup, 3 (5%) revised (all loose) + 2 loose; (ii) cup, 3 (5%) revised (loose) + 2 loose; (iii) no revisions or loosening; (i) vs. (ii), p , not significant for revision or mechanical failure rates). Failure rates of components – stem: HS2P, 5/33 (15%) (average follow-up 54 months); Omnifit, 2/83 (2%) (ave | A |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
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| Mallory, et <i>al.,</i> 1989 (USA) Unusual | Retrospective, controlled (i) AML, MHP, PCA, ceramic, SRN-REV (ii) Controls, uncemented, over same period with no fractures (no further details) (i) Porous- coated, cementless, porous-coated, ceramic, cementless. | Not specified ? Modified direct lateral | (i) 56 femoral fractures (ii) 56 controls Maximum follow-up: 60 months 111 | 50.4 years (21–81) Sex Primary or revision operation Diagnosis | Fracture types: Type I (n = 45) – AML 33%, MHP 31%, PCA, 24%, ceramic 7%, SRN-REV 5%; Type II (n = 9) – AML 33%, MHP 33%, ceramic 22%, SRN-REV 12%; Type III (n = 2) – PCA 100%. Improvement by operation (includes fracture types I and II): (i) Great/very great, 51/54 (94.4%); (ii) Great/very great, 47/53 (88.7%); p, not significant. Modified d'Aubigne–Harris Score, Types I and II only (p, not significant): Pain (a) preoperative, (b) postoperative: (i) (a) score 1/2, 27; 3/4, 27; (b) 3/4, 13; 5/6, 40; (ii) (a) I/2, 22; 3/4, 32; (b) 3/4, 10; 5/6, 44. Function (a) preoperative, (b) postoperative: (i) (a) 1/2, 18; 3/4, 35; (b) 3/4, 12; 5/6, 30; (ii) (a) 1/2, 4; 3/4, 49; (b) 3/4, 16; 5/6, 37; Range of motion (a) preoperative, (b) postoperative: (i) (a) 1/2, 4; 3/4, 49; (b) 3/4, 16; 5/6, 37; (ii) (a) 1/2, 6; 3/4, 47; (b) 3/4, 22; 5/6, 31. | |
| Maloney & Harris, 1990 (USA) | Retrospective, matched (i) Cemented Precoat stem + Harris-Galante Porous cup (ii) Harris- Galante stem and cup (i) Hybrid (ii) Porous | One senior surgeon General/ teaching hospital Not specified, but same for both groups | (i) 67 (ii) 69 Follow-up (range): (i) 32 months (24-46) (ii) 37 months (24-57) (i) 25 (ii) 25 | (i) 62 years (54-67) (ii) 61 years (55-69) Diagnosis Sex Weight | Harris Hip Scores: Matched pairs – pre- vs. postoperative mean (range): (i) 52 (38–67) vs. 96 (80–100); (ii) 48 (33–67) vs. 84 (35–100); postoperative comparison, $p < 0.02$. Overall group – pre- vs. postoperative mean (range): (i) 55 (28–70) vs. 97 (74–100); (ii) 57 (20–76) vs. 87 (35–100); (matched pair scores preoperatively did not differ significantly from equivalent original group scores). Pain: (i) 24/25 (96%) no or slight pain; (ii) 19/25 (76%) no or slight pain; p , ? Thigh pain: (i) None; (ii) 5/25 (20%); p, ? Limp: (i) 19/25 (78%) no limp, 5/25 (20%) mild limp; (ii) 11/25 (44%) no limp, 9/25 (36%) mild limp; p, ? Migration – cups: None or complete radiolucency in both groups. Migration – stems: (i) all radiologically stable, no migration; (ii) 5/25 (20%) radiologically migrated; p, ? Revisions: (i) None; (ii) 4/25 (16%) revised, 3 due to migration. | C |
| Markel, <i>et al.,</i> 1995 (USA) | Retrospective Cups: (i) all- polyethylene (Charnley) (ii) metal-backed (Charnley design) or TiBac design) plus Charnley stem Cemented cups | One senior surgeon Specialist hospital Posterior | 134 in 112 patients Mean follow-up (range): 84 months (49–120) (i) 90.6 months (ii) 78.4 months 115 in 97 patients (i) 55 (ii) 60 (21 Charnley, 39 TiBac) | (i) 62.8 years (ii) 58.6 years Sex Side of body Height Weight Diagnosis (variables listed but no data given) | Hospital for Special Surgery hip rating system (n = 115): (i) Good/excellent 55 (100%); (ii) Good/excellent 60 (100%). Rate of linear polyethylene wear: (i) 0.08 mm/y; (ii) 0.078 mm/y; p, not significant. Volumetric polyethylene wear rate: (i) 32.9 mm ³ /y; (ii) 30.3 mm ³ /y; p, not significant. Revisions/loosening (n = 108): No revisions, (i) 32% (16) probably loose; (ii) 16% (9) probably loose; p, not significant; (no stems loose). | С |

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|---|---|--|--|---|---|-------|
| McPherson, et al., 1995 (USA) | Retrospective, matching (material collected prospectively) APR-I (i) HA-coating added (ii) Porous-coat | Not specified Teaching hospital Not specified | 230 patients Follow-up: Minimum 3 years 84 patients | (i) 55 years (23-73) (ii) 56.5 years (22-71) Sex Weight (Also matched for Diagnosis Charnley activity and class; bone quality and type, and surgical technique but details not given) | Harris Hip Score – average (range): (i) 95.1 (65–100); 39 (93%) excellent/good; (ii) 95.8 (59–100); 41 (98%) excellent/good; p, not significant. Harris Pain and Limb Scores – no significant difference (no data given). Modified Engh Radiographic Fixation Score: Grade IA, B or C at 3 years: (i) 38 (90%); (ii) 35 (83%); p, not significant. Modified DeLee–Charnley Fixation Score (3 years): (i) Grade IA, 39 (93%); IB, 3 (7%); (ii) Grade IA, 26 (62%); IB, 14 (33%); IC, 2 (5%); (i) vs. (ii), p, 0.002; HA has better fixation. Revisions/loosening: Mechanical failure rate, (i) 5% – 1 revised (due to loosening) plus 1 unstable (loose?); (ii) 5% – 2 unstable (loose?). | с |
| Moilanen, et <i>al.</i> , 1996 (UK) | Prospective SLF press-fit cup (i) with HA-coating (ii) without HA-coating (+ Freeman stem, cemented or uncemented) (i) HA-coating (ii) Press-fit | Not specified Teaching hospital Anterolateral | 111 (i) 71 (ii) 40 Follow-up: (i) 2.3 years (ii) 3.4 years (i) 71 (two revised by 7 months and excluded from further analysis) (ii) 40 | (i) 59.7 years (ii) 62.6 years Sex Diagnosis | Number with pain requiring analgesics: (i) Preoperative, 66/69 (96%); +3 years, 0/30 (0%); (ii) Preoperative, 36/40 (90%); +3 years, 2/33 (6%); p, not significant. Number able to walk continuously for 30 minutes: (i) Preoperative 5/69 (7%); +3 years 22/30 (73%); (ii) Preoperative 5/69 (7%); +3 years, 26/33 (79%); p, not significant. Vertical linear wear at 3 years: (i) 0.07 mm \pm 0.19 (n = 15); (ii) 0.10 mm \pm 0.17 (n = 28); p, 0.61. Migration (mean): (i) rate 0.06 mm/y (ii) rate 0.20 mm/y; p, 0.22. Length of follow-up or migration level by 6 months neither affected the results nor predicted subsequent rate. Ceramic ((i) 40%, (ii) 23%) vs. metal femoral head did not affect rate. Radiolucent lines: (i) 3/52 (6%); (ii) 8/30 (27%); p < 0.0 Revisions: (i) 2 revisions, none due to loosening; (ii) no revisions. | ls |
| Moskal, et <i>al.,</i> 1994 (USA) | Prospective PCA (i) uncemented stem (ii) cemented stem (i) Porous-coated (ii) Hybrid | One senior surgeon Community hospital Modified direct- lateral, 97%; trans- trochanteric, 3% | 137 in 122 patients Follow-up: 2–4 years 134 | (i) 63 years (27–95) (ii) 75 years (51–92) Sex Height Weight | Harris Hip Score, preoperative vs. +3 years: (i) 43 (1–87) vs. 89 (51–100); (ii) 41 (1–100) vs. 86 (61–91); p , not significant. Harrris Pain Score, preoperative vs. +3 years: (i) 15 (0–44) vs. 41 (30–44); (ii) 15 (0–44), vs. 42 (40–44); p , not significant. Thigh pain: (i) +3 years, 5% incidence; (ii) no thigh pain Limp incidence: (i) 18%;(ii) 22%; p , not significant. Radiolucency: 6% hips had lines in each stem zone; 7/134 (5%) cups had lines in 2/3 zones; no revisions or loosening. | C |
| Nashed, et <i>al.,</i> 1995 (USA) | Retrospective BIAS stem (i) Titanium head, cemented polyethylene cup (ii) Titanium head, cemented metal- backed cup (iii) Titanium head, uncemented metal-backed cup (iv) Cobalt– chrome head, uncemented metal-backed cup (i, ii) Cemented vs. (iii, iv) Press-fit | One senior surgeon General hospital Not specified | 193 Follow-up (range): Total average 6.9 years (2.3–12.5) (ii) 9.4 years (4.3–12.5) (iii) 7.8 years (3.3–10.5) (iii) 6.6 years (4.3–8.0) (iv) 5.5 years (2.3–8.0) Total: 175 (i) 24 (iii) 62 (iiii) 15 (iv) 74 | (i) 50 years (ii) 52 years (iii) 51 years (iv) 50 years Sex Weight Diagnosis | Average wear rates: (i) 0.10 mm/y; (ii) 0.13 mm/y; (iii) 0.25 mm/y; (iv) 0.17 mm/y; p, ? Osteolysis (%) (stem lysis (%), cup lysis (%)): (i) 0 (0.00); (ii) 31 (24, 7); (iii) 87 (87, 40); (iv) 24 (22, 14). Incidence of osteolysis statistically higher in (iii) than any other group ($p < 0.001$) and statistically lower in (i) than in any other group ($p < 0.005$). Revisions: Hips with osteolysis 44%; without osteolysis 7%; p < 0.001. | С |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
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| Neumann, et <i>al.</i> , 1996 (Denmark) Unusual | Prospective Charnley (i) Patients 55 years or younger (ii) Patients older than 55 years Cemented | One senior surgeon Teaching hospital Lateral with trochanteric osteotomy | 240 in 211 patients (i) 52 (ii) 188 Median follow-up (range): (i) 17.0 years (15-20.6) (ii) 17.7 years (15.1–20.4) Total: 114 (i) 37 (71%) (ii) 77 (41%) | Overall median: 62 years (34–79) (i) 51 years (34–55) (ii) 64 years (56–79) Diagnosis Previous operation on hip | Charnley Scores: Pain – identical for both groups preoperatively and at each follow-up; Function:(i) median 5; (ii) median 44 at latest follow-up; (ii) probably due to deterioration in health Motion: no substantial differences between groups. Revisions/loosening: Revisions: (i) 5/52 (10%); (ii) 15/188 (8%); Loosening: (i) 3 (6%); (ii) 5 (3%); p, 0.37. Probability of survival at 20 years: (i) 88.3% (95% Cl ± 9.8%); (ii) 89.3% (95% Cl ± 5.8%); p, 0.82. | В |
| Pierchon, et <i>al.,</i> 1994 (France) Unusual | Retrospective (i) Dislocated prosthesis Stem: 29 Müller self-locking 5 Müller dysplasia 4 not specified Cup: 12 cemented 26 uncemented (ii) Controls (not dislocated): cup not specified Cemented and hybrid | Not specified Teaching hospital Posterolateral without trochanteric osteotomy | (i) 39 (1st dislocation, 22; recurrent, 16 + 1 exclusion) (ii) 14 (11 contra- lateral hips from (i)) Follow-up period not specified (i) 38 (ii) 14 | (i) 57 years (17–91) Sex Side of body Diagnosis (NB: for (i) only) | Mean cup abduction: (i) 44.5° (30–68°); (ii) 43.6°; p, not significant. Mean cup anteversion: (i) 24.2° (-5–45°); (ii) 22.3°; p, not significant. Mean femoral neck anteversion: (i) 16.5° (-30–37°); (ii) 14°; p, not significant. Revision: (i) 7 hips, all now stable. | C |
| Pritchett, 1995 (USA) | Retrospective (i) Müller Straight Stem (ii) Physiological Stress Loading (iii) AML (iv) Conical Collar (v) Harris Precoat (i) Cemented, collarless (ii) Porous- coated, collared (iii) Porous- coated, collarless (iv) Material not specified, collared (v) Cemented, collarless | Not specified Teaching hospital Not specified | 50 in 50 patients Follow-up: (i) 3.5-4.5 years (ii) 3-5 years (iii) 3-4 years (iv) 3-4 years (v) 3-5 years (i) 10 (ii) 15 (iii) 6 (iv) 13 (v) 6 | | Measured bone density loss compared with contralateral ('normal') hip: (i) -57% (-42, -85); (ii) -8% (+5, -30); (iii) -34% (-30, -60); (iv) -14 (+15, -30); (v) -43% (-36, -70). (i) vs. (iii) vs. (v), p, not significant; (ii) vs. (iv) p, not significant; (i), (iii), (v) vs. (ii), (iv) $p < 0.05$. Those with collar associated with less bone density loss in proximal femur. Bone mineral density in contralateral hips similar in all groups (72% hips within 10% of average value). | C |
| Pupparo & Engh, 1989 (USA) | Prospective AML stem with (i) S-ROM Anderson cup (smooth- threaded) (ii) S-ROM Super cup (porous- threaded) | One surgeon, grade not specified Not specified Posterolateral | (i) 82 (? patients) (ii) 62 (? patients) Follow-up (range): (i) 33.3 months (24–49) (ii) 29.5 months (25–50) (i) 56 (68%) (ii) 41 (66%) | Age not specified Weight Diagnosis | d'Aubigne Score (mean): (i) pain 5.59 ; walking 5.54; (ii) pain 5.68; walking 5.50. Migration: (i) 16 (29%) unstable, nine had migrated by mean 5.5 mm (3-11 mm); (ii) all stable, no migration; p < 0.001. Revisions/loosening; | C |

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| | design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
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| tanawat, t al., 1988 USA) Jnusual | 988matchedSpecialist hospital Specialist hospital (i) 5 years, average 10 years (8-12)Follow-up (range): Sex (i) 5 years, 0 (0%).(i) 5 years, 4 (8%); 10 years, 5/37 (2–5 mm) (14 (ii) 5 years, 0 (0%).10(i) 23; (ii) 35Not specified10 years (8-12)Weight DiagnosisRadiolucency: Cumulative score lower in (ii) than (i), p, 0.000 (i) 7 (14%) with score of 4 or more; (ii) 1 (2%) with score of 4 or more.(i) 6; (ii) 05 years, 100 hips (i) 3; (ii) 2(ii) 10 years, 37 hipsRevisions/loosening: (i) 10 years, 37 hips(i) 3; (ii) 2(ii) 10 years, 37 hipsRevisions/loosening: (i) no cup/stem revision required 5 years (1 re due to socket migration at 8 years); | | (i) 5 years, 4 (8%); 10 years, 5/37 (2–5 mm) (14%); (ii) 5 years, 0 (0%). Radiolucency: Cumulative score lower in (ii) than (i), p, 0.0005; (i) 7 (14%) with score of 4 or more; (ii) 1 (2%) with score of 4 or more. Revisions/loosening: (i) no cup/stem revision required 5 years (1 revision due to socket migration at 8 years); (ii) no cup revision required for loosening; 1 stem | В | | |
| Aand & Ilstrup, 983 USA) | Retrospective, matched (i) Charnley (ii) T-28 Cemented | 20 surgeons, grades not specified Not specified Not specified | (i) 2388 in 2388 patients (ii) 459 in 459 patients Follow-up: (i) 5.7 years (± 0.7) (ii) 5.2 years (± 1.7) (ii) 40 (ii) 40 | (i) 64.7 ± 7.2 years (ii) 64.0 ± 8.1 years Sex Side of body Diagnosis Contralateral THR Previous surgery Number of trochanteric osteotomies | Pain: (i) 38/40 (95%), no/slight pain; (ii) 37/40 (92.5%), no/slight pain. Use of ambulatory aids: (i) 37/40 (92.5%), no aids; (ii) 38/40 (95%), no aids. Migration/subsidence: (i) 13 (32.5%) cup migrated > 1 mm; 8 (20%) stem subsided > 1 mm; (ii) 9 (22.5%) cup migrated > 1 mm; 8 (20%) stem subsided > 1 mm. Radiolucent lines (> 1 mm): stem - (i) 3; (ii) 5; p , not significant; cup: (i) 8; (ii) 17; p, not significant. Revisions/loosening: 1 hip in each group revised due to aseptic loosening. | с |
| kiska, 1993 Finland) | Retrospective Ceraver Osteal alumina on alumina prosthesis with titanium alloy stem and: (i) cemented cup (ii) uncemented screw cup Cemented ceramic vs. uncemented ceramic | One surgeon, grade not specified Teaching hospital Anterolateral (McKee) | 290 in 55 patients (i) 143 patients (ii) 112 patients (three already excluded) Follow-up (range): (i) 6.7 years (1–12) (ii) 3.6 years (1–7) (i) 143 (ii) 112 | 62 years (25–86) Sex Diagnosis | Charnley Scores: All without revision had excellent/good scores; scores averaged 4–6 for all sections. Revision/loosening: (i) revision, 16 (11.2%); loosening, 12 cups, 1 stem, 1 both; (ii) revision, 7 (6.3%); loosening, 2 cups; p, ? | С |
| kitter & Gioe, 986 USA) | Prospective (i) T-28 (ii) Indiana conservative hip (i) Cemented (ii) Resurfacing | Not specified Teaching hospital Transtrochanteric (n = 85); anterior (n = 15) | 100 in 50 patients Follow-up: Minimum 5 years, maximum 7 years 90 in 45 patients | 62 years (21–87) Sex Diagnosis | Pain: Hospital for Special Surgery hip rating system (excluding revised hips): (i) Preoperative mean, 3.1; +5 years, 5.5; (ii) Preoperative mean 3.1; +5 years, 5.6; p, not significant. Revisions/loosening: (i) 2 revised (none loose); (ii) 15 revised (6 acetebular, 1 femoral, 4, both loose); patients with resurfaced hips requiring revisions were younger – average age 55 years. | с |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
|---|--|--|---|--|--|-------|
| Ritter, 1995 (USA) | Retrospective Charnley (n = 260) Müller (n = 163) T-28 (n = 642) MOSC (n = 319) (a) cemented all- polyethylene cup (b) cemented metal-backed cup Cemented | One MD Specialist centre/ teaching hospital Transtrochanteric | 1384 Follow-up range: Overall 1–22 years Average 8.9–12.7 years Failure analysis 1172; survival analysis 1144 | Range of average ages 59–76 years Sex Diagnosis | Number failed 1-year post-surgery: Charnley, 32 (14%); Müller, 29 (20%); T-28, 57 (10%); all-polyethylene MOSC, 9 (9%); metal-backed MOSC, 28 (20%). Survival analysis – % survival < 90% by: Charnley: 10 years, 93%; 20 years, 76%; Müller: 10 years, 81%; 17 years, 56%; T-28: 10 years, 93%; 17 years, 55%; all-polyethylene MOSC: 10 years, 90%; 12 years, 87%; metal-backed MOSC: 10 years, 60%. | с |
| Schreiber, et al., 1993 (Switzerland) | Retrospective (data collected prospectively) Balgrist with outer split ring of: (i) high density polyethylene (including 61 with 6 m of titanium) (ii) titanium alloy Press-fit | Not specified Teaching hospital Not specified | 717 in 644 patients (i) 346 in 309 patients (318 primary; 28 revision) (ii) 371 in 335 patients (280 primary; 91 revision) Follow-up (range): (i) 55.4 months (1–116) (ii) 15.6 months (0.5–60) (i) 282 patients (ii) 324 patients | (i) 53.8 years (23–76) (ii) 56 years (24–57) Sex | Revisions: (i) primary: 42/317 (13%); revisions: 6/29 (21%); (ii) primary: 2/280 (0.7%); revisions: 5/91 (5%); p, ? | С |
| Schuller & Marti, 1990 (The Netherlands) | Retrospective Weber type (i) metal rotating head (ii) ceramic rotating head Cemented vs. ceramic | One senior surgeon Teaching/private hospital Not specified | (i) 48 (ii) 46 Mean follow-up (range): 10 years (9–11) (i) 33 (ii) 33 | (i) 69 years (61–78) (ii) 66 years (48–78) Sex Weight Osteoarthritis | Wear of polyethylene: (i) mean 0.96 mm; (ii) mean 0.26 mm; $p < 0.001$. Revisions/loosening: (i) revision, 1 cup, 2 stems (9%) due to loosening; loose: 2 cups, 2 stems (12%); (ii) revision: 1 cup, 1 stem (6%) due to loosening; loose: 2 cups, 1 stem (9%). Rate of aseptic loosening, p , not significant. | С |
| Turner, 1994 (USA) | Retrospective (i) Aufranc- Turner (ii) Harris Design 2 (15 mm) (iii) Omnifit/ Omnifit/ Omnifitx (iv) Tharies (v) Kirschner Murray Welch (11 mm) (vi) Charnley- Müller (15 mm) (vii) Kirschner Anatomic (13 mm) (viii) Harris- Galante (11 mm) (ix) Biofit (14 mm) (x) Ring (xi) Dupuy Engh- Anderson (xii) Bichat (xiii) Intermedic (xiv) Stackhouse (xv) AML (15 mm) Various | By, or supervised by, one MD General hospital Anterolateral, 9%; posterolateral Kocher (Langenbeck) 91% | 564 Follow-up period not specified 561 | Age not specified Sex | Dislocation rates: (i) 4/129, 3.1%; (ii) 5/74, 6.76%; (iii) 4/74, 5.5%; (iv) 1/56, 1.8%; (v) 2/56, 3.57%; (vi) 0/53, 0%; (vii) 0/34, 0%; (ix) 2/34, 5.88%; (x) 1/7, 14.3%; (xi) 1/5, 20%; (xii) 0/1, 0%; (xiii) 0/1, 0%; (xiii) 0/1, 0%; (xiv) 1/1, 100%; (xv) 0/1, 0%. Anterolateral, 0/53, posterolateral, 25/508 (4.9%). Primary operation: 19/477 (4%); revision, 6/84 (7%). Men: 6/215 (2.8%); women: 19/346 (5.5%); p, not significant. | C |

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| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|--|--|---|---|--|--|--------|
| Visuri, et <i>al.,</i> 1994 (Finland) | Retrospective (i) McKee-Farrar (ii) Brunswick (iii) Lubinus Cemented | Not specified Specialist hospital Not specified | Basic material, 1863 hips/patients; study group, 1018 in 1018 patients) Follow-up: 12 years Total: 1018 (i) 237 (ii) 449 (iii) 332 | Men 61 years Women 63 years Sex Diagnosis | 10-year survivorship of patient (not hip): (i) 85% alive (95% CI: 79–89) (n = 202/237); (ii) 82% alive (95% CI: 78–85) (n = 367/449); (iii) 82% alive (95% CI: 77–86) (n = 133/332 estimated). 10-year survivorship (sex): men 77%; women 86%. 10-year survivorship after 65th birthday: 78% (men 69%, women 83%). | с |
| Walker, et <i>al.</i> , 1995 (UK) | Retrospective (data collected prospectively) (i) Charnley (ii) Stanmore Cemented | Several surgeons, grade not specified Specialist hospital Not specified | Originally 403 patients (a): (i) 51, (ii) 57 (b): stable (i) 23, (ii) 23; revised (i) 17, (ii) 29; Total (i) 40, (ii) 52 Follow-up (range): (a): 5.8 years (1–12) (b): stable minimum 8 years; revised 79 months (11–218); (a): (i) 49; (ii) 55 (b): (i) 40 (23 stable, 17 revised) (ii) 52 (23 stable, 29 revised) | (a) not specified (b) 63 years Sex Diagnosis | Stem subsidence (a): Identical, mean against time, p , not significant (mean migration: 0–6 months 1.39 mm; 0–1 year 1.93 mm; 0–5 years 2.68 mm; 0–9 years 3.42 mm). Data given as a combined group (migration rate: 0–6 months 1.82 mm/y; 6–12 months 0.96 mm/y; 1–2 years 0.54 mm/y; 2–9 years 0.21 mm/y). Stem subsidence (b): stable: +2 years 35/46 (76%), migrated < 2 mm; revised: +2 years 35/46 (15%), migrated < 2 mm; p < 0.001. Radiolucent zone (around entire cement–bone interface): stable: 2%; revised: 89%; p,? Migration at interfaces: stable – 7% stem–cement; 77% cement–bone; 17% both; revised – 34% stem–cement; 0% cement–bone; 66% both; p,? | c |
| Wilson- MacDonald & Morscher, 1989 Switzerland) | Retrospective (i) Müller standard-stem (ii) Müller straight stem (iii) collared stem derived from long-stem steel prosthesis (130 mm stem, neck shaft angle 130°) (plus RM cup in all hips) Cemented | 12 senior surgeons Teaching hospital Lateral without trochanteric osteotomy | 545 in 518 patients (i) 76 (14%) (ii) 370 (68%) + 11 (2%) lateralised version (iii) 88 (16%) Follow-up: 5–10 years Clinical analysis not specified; radiographic examination 411 patients | 65.2 years (29–89) Sex Diagnosis | Radiographic loosening: (i) + (ii) 8%; (iii) 11%; p , 0.02. Subsidence > 5 mm: (i) + (ii) 2.85%; (iii) 4.5%; p , not significant; subsidence > 2 mm without radiological evidence. (ii) 10.8%, 32 hips. Radiographic loosening of RM cup: (i) + (ii) 35%; (iii) 7%; p , 0.03; (i) vs. (ii) p , 0.002. Revisions/loosening (including deceased patients): 41 revised in total, 20 stems revised; (i) revised, 5/76 (6.57%), 3 loose (3.94%); (ii) revised, 10/381 (2.62%), 6 loose (1.57%); (iii) revised, 5/88 (5.68%), 4 loose (4.54%). | c |

DATA TABLE 2 contd Non-controlled comparative studies included in the review

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Ratin |
|--|--|---|---|--|--|--------------|
| Wixson, et <i>al.,</i> 1991 USA) | Prospective Stem: Uncemented: PCA, 65 Cemented: PCA, 30; Six Ti/28, 15; ATS, 14; HD-2, 18; CDH, 2 Cup: Uncemented: PCA, 84; Harris- Galante, 6; APR, 1 Cemented: PCA, 10; TiBac, 40; Harris, 3 Cemented Porous Hybrid | Two MDs Teaching hospital Posterior | 197 in 176 patients Follow-up: Mean 2.8 years (maximum 4) 144 in 131 patients | 61.1 years Sex Diagnosis | Harris Hip Score: cemented – preoperative 100% fair/poor; most recent 77% excellent/good; mean at 4 years, 91; uncemented – preoperative 99% fair/poor; most recent 89% excellent/good; mean at 4 years, 90; hybrid – preoperative 100% fair/poor; most recent 89% excellent/good; mean at 4 years, 95; p, not significant. Harris Pain Score (preoperative vs. most recent follow-up – mean): cemented: 16 vs. 42, 84% no/slight pain; uncemented: 16 vs. 43, 98% no/slight pain; uncemented: 16 vs. 43, 98% no/slight pain; p, ? Thigh pain at 3 years: cemented stem, 3%; uncemented stem, 13%; p < 0.05. Need for walking aids: cemented – preoperative 80%; most recent 23%; uncemented – preoperative 57%; most recent, 11%; hybrid – preoperative 70%; most recent 29%; p, ? Migration/subsidence: cemented – cup, 6 (12%) migrated or changed position; stem, no subsidence. uncemented – cup, 3 (3%) changed position; stem 3 (5%) subsided. Revisions/loosening: cemented – 2 (3.8%) revisions (due to loosening); uncemented – 5 (7.7%) revisions (4 loosening); hybrid – 1 (3.7%) revision (no loosening). | C |
| fahiro, et al., 1995 Various) | Meta-analysis (i) Threaded cup (Mecring, T-TAP, S-ROM, Accu- Path, Link V) (ii) Porous- coated prosthe- sis (PCA, AML, Harris-Galante, Whitesides, APR, BIAS) (iii) Cemented prosthesis (Charnley, Aufranc-Turner, Müller or Dual- Lock, Harris or HD-2, STH-2, T-28, Stanmore or PCA, AlloPro, CAD) | Not specified | (i) 1269 (ii) 1979 (iii) 10,230 Follow-up (range): (i) 2.2 years (0.5–6.3) (iii) 3.6 years (0.2–9) (iii) 7.5 years (0.2–23.1) As above | (i) 51.2 years (20-91) (ii) 50.3 years (16-92) (iii) 61.1 years (14-99) Sex Diagnosis | Diagnoses of revisions of failed previous operations: (i) 30.7%; (ii) 8.4%; (iii) 13.5%; ('significantly more in (i)'; p, ?). Incidence of cup failures (clinical): revision rate – (i) mean 3.58%, (ii) mean 1.44% [#] , (iii) mean 1.61% [#] ; migration – (i) mean 8.85%, (ii) mean 0.64% [#] , (iii) mean 1.61% [#] ; migration – (i) mean 15.10%, (ii) mean 3.01% [#] ; (iii) mean 4.53% [#] ; ([#] all significantly different from (i) $\alpha < 0.05$). Incidence of cup failures for revision subgroup: revision rate – (i) mean 14.59%; (ii) 3.68%; (iii) 3.35%; (i) vs. (ii), and (i) vs. (iii) $\alpha < 0.5$. migration: (i) mean 17.56%; (ii) 12.50%; (iii) 8.18%; (i) vs. (iii) $\alpha < 0.5$. Incidence of cup failures (radiolucencies): progressive – (i) mean 7.64%; (ii) 1.97%; (iii) 6.08%. (i) vs. (iii) (i) vs. (iii) $\alpha < 0.5$. > I mm: (i) mean 55.15%; (ii) 12.49%; (iii) 19.07%; (i) vs. (iii) $\alpha < 0.5$. complete: (i) mean 3.31%; (ii) 3.58%; (iii) 2.33%. incomplete: (i) mean 52.45%; (ii) 60.70%; | Not rated |

| Study (country) | Study design and prosthesis type | Grade of surgeon, type of hospital, and surgical technique | Number of THRs, length of follow-up and number of patients followed-up | Patient age; other patient variables reported | Outcome measures and results | Rating |
|---|---|--|--|---|--|--------|
| Zicat, et <i>al.</i> , 1995 (USA) | Retrospective Stem: All AML or P10 (32 mm head) Cup: (i) cemented all- polyethylene (ii) AML cup (i) Cemented (ii) Porous- coated | One senior surgeon Specialist hospital Not specified | (i) 63 in 63 patients (ii) 74 in 74 patients Follow-up (range): (i) 107 months (54-142) (ii) 102 months (62-122) (i) 63 (ii) 74 | (i) 57 years (24-85) (ii) 54 years (16-79) Sex Weight Diagnosis Charnley class Side of body | (ii) 13/71 (18%) cups had expansile osteolysis | |
| Zichner & Willert, 1992 (Germany) | Retrospective Müller-type with femoral heads: (i) Protasul-2 (ii) Protasul-10 (iii) Ceramic Cemented vs. ceramic (Metal vs. ceramic heads) | Not specified but same surgeons for each group Not specified (Probably teaching hospital, but same clinic) Not specified but same technique for all | 354 in 313 patients (Original cohort number unknown) (i) 149 (ii) 105 (iii) 100 Follow-up (range): (i) 66 months (30–108) (ii) 46 months (30–84) (iii) 73 months (30–102) 354 | Not specified | Displacement rates (wear rates): (i) in those requiring revision, all > 0.2 mm/y, 40% > 0.3 mm/y; in non-revision group, 40 (29.9%) > 0.2 mm/y, 11 (8.2%) > 0.3 mm/y; (ii) in those requiring revision, all > 0.2 mm, 4 > 0.4 mm/y; in non-revision group, 20 (20%) > 0.2 mm; (iii) $63\% < 0.1$ mm/y, 95% < 0.2 mm/y, no prosthesis > 0.3 mm; p, ? Revisions/loosening: (i) 15 (10.0%) revised due to loosening; (ii) 5 (4.8%) revised due to loosening; (ii) 2 (2%) revised due to loosening; p, ? | с |

Data tables of observational studies

Studies are grouped in the following order: Charnley studies, other cemented models, cementless porous-coated, cementless HA-coated, cementless uncoated press-fit, hybrid, cementless mixed, threaded cups.

The results presented in the tables are for the latest follow-up unless otherwise stated. Scores given for clinical rating systems (e.g. Harris) are means for the patient groups unless otherwise stated. Where numbers of hips followed-up are given in parentheses (e.g. (222)), this refers to the number in the total series, the actual number reviewed for the published study then being given separately, and not in parentheses.

The 'total mechanical failure' rate is the number of revisions plus failures as defined by radiological criteria; these vary from study to study but generally include definitions of loosening, migration, stability, and fracture of components.

| Study, country, rating | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|--|---|--|--|
| Ahnfelt, et <i>al.,</i> 1990 Multicentre registry, Sweden C | 15,520 Charnley only 1799 at 10 years (10 years) | Not specified for subgroup | Survival 92% at 10 years | |
| Brady & McCutchen, 1986 USA C | (170) 155 followed-up (10 years) | Not specified | Revision rate 8.8%; n = 3 revisions for loose stem | 3 revisions in heavy patients at 9 years; 1st generation cementation – precise technique |
| Carlsson, <i>et al.,</i> 1986 Sweden B/C | 207 68.7% (207 osteoarthritis, 34 rheumatoid arthritis) (5–12 years 5 months (osteoarthritis)) (3.4–12 years (rheumatoid arthritis)) | Not specified | Osteoarthritis 26% Ioosening; rheumatoid arthritis 34% Ioosening | |
| Carter, et <i>al.,</i> 1991 UK C | 1616 31% (10–20 years) | Not specified | Survival 91% at 10 years; survival 82% at 20 years | |
| Collis, 1988 USA C | 180 37% (10+ years) | Not specified | 3.3% revision | |
| Dall, et <i>al.</i> , 1988 South Africa B | 98 (mean 12 years, range 10–14) | Mean 61 years 87% > 50 years | n = 4 (4%) stems loose; 14% revised – 4 loose cups, 1 stem loose, 7 stem fracture 2 recurrent dislocations, hence, 5% revisions for loose + 6% radiography failures | Osteoarthritis 76% |
| Dall, et <i>al.</i> , 1988 South Africa Not rated | 2059 (mean 10 years 5 months, range 3–17 years) | Not specified | 9.1% total revision rate (loose cup 2.1%, loose stem 4.9%); + 6% possible radiography failure | Ist generation stems fractured more frequently but more loosening in stiffer 2nd generation stems |
| Dall, et <i>al.,</i> 1993 South Africa B | 811 Charnley 66.2% (10–12 years) | Mean 60 years (range not specified) | Survival 87% at 10–12 years; 8% revised | |
| Eftekhar, 1987 USA C (see also Eftekhar & Tzitzikalakis, 1986 below) | 1009 (20% revision/conversions) 69% (5–15 years) | Not specified | 2.0% revisions; 3.8% mechanical failure | |
| Eftekhar & Tzitzikalakis, 1986 USA B (same patients as previous) | 499 primaries + 197 revisions (696) (5–15 years; just over 25% followed-up at > 10 years; mean not specified) | Mean 62.4 years; range 22–67 years | 4.5% total mechanical + infection failure rate 2.2% re-operation of primaries, + 1.2% (n = 6) pending failure | 48% osteoarthritis; single surgeon |
| Garcia-Cimbrelo & Munera, 1992 Spain A | 680 60% at 10 years (18 years) | Mean 56 years; range 18–79 years | Survival 81% at 18 years; survival 91.6% at 10 years; pain 4.6 at 17 years (d'Aubigne-Postel and Charnley); walking 4.6 at 17 years; range of motion, 4.4 at 17 years | |
| Gudmundsson, et al., 1985 Denmark B | 186 67.2% (n = 125) (10-14 years) | Median 71 years; range 31–85 years | 29% loosening; 86% no/slight pain; 58% normal/ slightly limited range of motion | District General Hospital |
| Hamilton & Joyce, 1986 Canada B (same patients as Hamilton & Gorczyca, 1995) | (450) 230 followed up for 3–11 years about 100 at 6 years | 86% > 50 years | Revision rate as loose: cup 0.7%, stem 0.0%; n = 14 stem subsidence; n = 6/230 cup migration (2.6%) | Community hospital; large percentages of death and loss to follow-up not accounted for; 61% patients dislocation/childhood conditions, etc.; single surgeon; Charnley method; flanged versions introduced during study |

DATA TABLE 3 Observational studies: Charnley

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DATA TABLE 3 contd Observational studies: Charnley

| Study, country, rating | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|---|---|---|---|--|
| Hamilton & Gorczyca, 1995 Canada B (same patients as Hamilton & Joyce, 1986) | 224 83% at 10 years (minimum 10 years (maximum 20 years) mean not specified) | Mean 58 years | Mean d'Aubigne score between 5 and 6 every year except 19th. 12.5% cup migration; 6.7% cup revision; 2.6% (n = 5/188) stem migration/ subsidence/ fracture, 6.3% stem revision | Shows strong association between wear and migration/revision; single surgeon |
| Hartofilakidis, et <i>al.,</i> 1989 Greece B | 104 89% (10–14 years) | Mean 57 years; range 24–82 years | 78.5% asymptomatic 5.5 pain 5.1 function 4.9 motion | 20% total revisions (7% for aseptic loosening) |
| Hodgkinson, et <i>al.</i> , 1993 C | Cup; unflanged 152 83.5% (1–10 years) | Not specified | 30.3% no radiological demarcation at 10 years | |
| Hodgkinson, <i>et al.,</i> 1993 (same study as above) (see Comparative studies) | Cup; flanged 150 89.3% (1–10 years) | Not specified | 42.7% no radiological demarcation at 10 years; flanged compared with randomly selected unflanged. Flanged socket better than unflanged by radiography criteria at 10 years, statistical significant. Previously revised hips excluded | lly |
| Johnsson, <i>et al.</i> , 1988 Sweden C | 204 100% (4-14 years) | Males: median 65 years, range 36–87 years; females: median 67 years, range 47–84 years | Revisions 14.7% | |
| Johnston & Crowninshield, 1985 USA C | 326 55.8% (n = 182) (10 years) | Not specified | 9% femoral loosening; 7.9% acetabular loosening | |
| Joshi, et <i>al.</i> , 1993 UK A | (218) 166 (mean 16 years, range 10–24 years) | Mean 32 years, range 16–40 years | At 20 years: total survey 75%; stem surgery 86%; cup surgery 84%; Aseptic loosening: stem: 3% at 10 years; 14% at 20 years; 16% at 20 years; 4% stem subsided > 5 mm | Wrightington; survival analysis and SEMs; significantly greater failure ris in years 10-20, and in osteoarthritis compared with rheumaoid arthritis (osteoarthritis risk of revision 20% at 10 years, nearly 49% at 20 years) small head, tapered stem |
| Karachalios, et <i>al.,</i> 1993 Greece C | 95 Charnley 57.9% (12–18 years; average 13 years 5 months) | Not specified | 27.4% cups migrated; 15.8% stems subsided; survival related to centre of rotation of prosthesis and body weigh | |
| Kavanagh, et <i>al.</i> , 1989 USA C | 333 49.8% (15 years) | Males: mean 65 years, range 38–85 years; females: mean 64 years, range 39–84 years | Probability of failure: at I yea 0.9%; 5 years, 4.1%; 10 years, 8.9%; 15 years, 12.7% | r, |
| Kobayashi, et <i>al.,</i> 1994a; 1994b USA/Japan (2 studies) A/B | (703) 326 stems followed-up for mean 13 years 3 months 328 cups followed-up for mean 13 years 2 months (10–20 years) | Mean 58 years, range 18–79 years | Charnley mean 16.1 (max. 18) 1.2% (4) stems revised; 4.9% (16) radio- logically stem fix failure. 7.4% (24) sockets revised; 17% (56) radiological failure; n = 9/703 revisions for stem fail excluded from the follow-up series | Factors in mechanical loosening study, e.g. canal width; about 1/3 congenital dysplasia, about 1/3 osteoarthritis; includes table of 12 previous > 10-year follow-up studies of radiographically diagnose Charnley cup failures for aseptic loosening (this study is the largest) |
| Langlais, <i>et al.,</i> 1995 France Not rated | (446) 48 (mean 6 years 5 months) | | 11% trochanteric non-union1.3% (6) re-operations forinstability | 48 followed-up for mechanism of loosening, osteolysis; stems only followed-up |

| Study, country, rating | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|--|---|---|--|
| Madey, et <i>al.,</i> 1997 USA A/B | 356 142 followed-up (minimum 15 years) | Mean 69 years, range 24–88; for > 15-year follow-up, mean 62 years | Total revision rate 9%, 5% for aseptic loosening. At minimum 15 years: total revision rate for aseptic loosening, 11% (stem 2%, cup 10%) | Patient satisfaction measured; survival analysis; relatively high dislocation rate attributed to small head; 2nd generation cement technique; single surgeon |
| McCoy, et <i>al.,</i> 1988 USA A/B | 100 40% (15–17 years) | Mean 60 years, range 25–84 years | 87.5% excellent/good, 7.5% fair, 5.0% poor; 90.8% survival at 16 years; 96% survival at 15 years, cup only | |
| Neumann, <i>et al.</i> , 1996 Denmark B (see Comparative studies) | 240 (15–21 years) | Young compared with older groups (see Comparative studies) | 20 year revision rate for 11.7% younger patients; 10.7% for older; no significant difference between groups | Near-complete follow-up |
| Neumann, et <i>al.</i> , 1994 Denmark B (superseded by Neumann, et <i>al.</i> , 1996) | 241 96% survivors (n = 103) (15-20 years) | Median 62 years, range 34–79 years | Probability of revision 10.7% at 20 years; 7% < 3 for pain movement (Charnley score) 30% loosening | |
| Nicholson, 1992 New Zealand C | 185 100% (15–22 years) | Not specified | Revision > 13%; cup loosening 17.7%, survival 90.9%; stem loosening 21.9%, survival 88.1% | |
| Older & Butorac, 1992 UK B | 388 34% (17–21 years) | Mean 68 years, range 42–85 years | Revision 6%; loosening 17% cups, survival 89% at 20 years (cup and stem) | District General Hospital |
| Older, 1986 UK C | 217 70.5% (n = 153) (10–12 years) | Median 64 years, range 42–55 years | 88% satisfactory; 6% revision; 92% patients satisfied | |
| Picault & Michel, 1995 France C? | 786 for 10–15 years 290 for 15–19 years 107 for 15–23 years (15–23 years) | Not specified | d'Aubigne (15–20 years): pain 5.8; mobility 5.7; walk 5.4; 84% pain-free at 15 years; 7.7% stem subsidence; survival 85% | |
| Ranawat, et <i>al.,</i> 1989 USA Not rated | 152 (17+ years) | Not specified | 72% survival (revision) | |
| Rasmussen, et <i>al.,</i> 1991 Denmark B ? | 95 (10 years) | Not specified | Survival 85%; 14/15 revisions for aseptic loosening; 71% pain free (82% of non-revised); stem subsidence (> 5 mm) in 9% | |
| Schulte, <i>et al.,</i> 1993 USA C | 322 Charnley 98.5% (20+ years) | Mean 65 years, range 29–86 years | 90% survival (retained implant); 85% pain free; 53% no walking aids; 10% revised | |
| Skeie, <i>et al.,</i> 1991 Norway A | 629 Charnley 89.7% (10–15 years) | Mean 66 years, range 23–88 years | 92% survival at 13 years; 86% patients good result; 7% revised | District General Hospital |
| Solomon, <i>et al.,</i> 1992 USA B/C | (156) 130 Mean 10 (3-16 years) | Mean 38 years; all < 50 years, 53% 41–50 years | Mechanical failure survival 88% at 10 years; radiological loosening in 12%; d'Aubigne mean score 14.8 | Contains table (9) reviewing published cemented results in your patients; follow-up range 2 years 8 months–12 years; revisions for mechanical failure in follow-up > 5 years, 2.6–21.2% |
| Stauffer, 1982 USA B | 207 90% (10 years) | Mean 64 years, range 39–84 years | Revisions 10.8%; cup loosening 11.3%, stem loosening 29.9% | |
| Sullivan, <i>et al.</i> , 1994 USA A/B | (89) 84 (mean 18 years, range 16–22 years) | Mean 42 years, range 18–49 years | Cups 13% (11) revised for aseptic loosening; stems 2% (2) for mechanical failure; survival for aseptic loosening: cup 76% \pm 12; stem 92% \pm 12; total mechanical failure including radiographically: cup 50%, stem 8% (> 5 mm) | Survival + Cls; good follow-up rate: polished stem; old cementation; single surgeon |

DATA TABLE 3 contd Observational studies: Charnley

| Study, country, rating | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|---|--|--|---|
| Terayana, 1986 Japan C | 107 (> 5 years) | Not specified | At 5 years: n = 1 revision for loosening + 1 pending; loose cup in +2, stem subsidence in +2, 2 conversions (8/107 failures, 7.5%) | Most patients women; 50% osteoarthritis secondary to congenital dysplasia |
| Thomas & McMinn, 1991 UK C | 1069 Charnley (10+ years) | Not specified | 92% survival at 10 years; no improvement following change of cement techniques | |
| Wejkner & Stenport, 1988 Sweden B | 325 50% (10–14 years) | Mean 64 years, range < 30 to > 80 years | 56% excellent, 28% good, 8% fair, 8% failure (Charnley scores) | |
| Welch, et <i>al.</i> , 1988 USA B/C | (100) 97 but small numbers followed-up (15–17 years) | Mean 65 years, range 30–88 years | 16% revised; mean time to revision, 10.8 years | 72% osteoarthritis |
| Wroblewski, 1986 UK B | 116 Charnley (15–21 years) | Mean 53 years, range 20–71 years | 85.3% pain free; 78% full range of movements; subsidence 29%; socket migration 22.5% | |
| Wroblewski & Siney, 1993 UK (Wrightington) C | 1324 Charnley 193 reviewed (18–26 years, average 10 years) | Mean 47 years, range 24–68 years | Dislocation 0.63%; revisions not specified, estimated as about 13–14% from survival graph (dislocation + stem fracture + loosenings) 16 years (from 1 infection 0.3–1.5%; pain free 85% (from normal function 60% | 324); |

DATA TABLE 3 contd Observational studies: Charnley

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|---|--|---|---------------------------------------|---|--|
| Ballard, et <i>al.</i> , 1994 USA A/B | Single surgeon; 2nd generation cemented technique; mixed prosthesis designs | 42 (mean 11 years, range 10–15 years) | Mean 41 years, range 18–49 years | About 25% (n = 10) revisions (10 cups aseptic loosening, 2 stems) | Severe disease, some failures in two young patients; three patients receiving renal dialysis. |
| Bosco, <i>et al.,</i> 1993 USA A/B | CAD and HD-2; 2nd generation cemented technique | 86 (48 + 38) (mean 6 years 7 months or 6 years 4 months, range 2–14 years) (67 followed-up for minimum 5 years) | | Hospital for Special Surgery rating: 71% satisfactory; 5.8% (n = 5) revised for aseptic loosening (3 for both components, 1 stem, 1 cup); 10-year survival rate: $age > 60$ years, 57% \pm 20; $age < 60$ years, 50% \pm 22; difference not significant; radiographically: 22% definite cup failure; 30% definite/possible stem loosening. | No significant difference reported between designs but no data given; weight not associated with radiographic cup outcome; borderline association stem outcome/weight; no association age/outcome; no significant difference earlier/later implants; significant correlation radiographica criteria/clinical score. |
| Dorr, <i>et al.,</i> 1994 USA C | Various: Charnley or Charnley–Müller, Aufrance–Turner, LeGrange– Letournel | 49 (mean 16 years 2 months) | Mean 31 years, range 16–45 years | d'Aubigne, 27% satisfactory; 67% revised for aseptic loosening. All patients aged < 30 years revised or pending; 13/16 cups and 3/25 stems pending revision. | 20 osteoarthritis Reviews other studies with high cup failure in very young patients; recommends non-arthroplasty treatment. |
| Fowler, et <i>al.</i> , 1988 UK B | Exeter; early cementation | 241 at 5–10 years 121 at 11–16 years (mean 13 years 4 months, range 11–16 years) | | Total mechanical failure 11% (revision rate, not specified); 1.64% stem loose; 3.9% cup loose; 5.4% fractures (attributed to early struc- tural defect); cups revised, n = 6; 74% stems no sign of loosening. | 73% osteoarthritis; includes 5-year follow-up of 2nd generation cemented series; extensive radiographic analysis. |
| Harris & Penenberg, 1987 USA B/C | Metal-backed cup, maker not specified | (48) 29 primary (mean 11 years 5 months, range 10–13 years 5 months) | Mean 44 years, range 34–76 years | Mean Harris score, unrevised 92; no revisions for loosening; 13.8% (n = 4) radiographic loosening. | 12.5% (48) revised for loosening; revisions age-related. |
| Hirose, et <i>al.,</i> 1995 USA B | Variety of designs; all stems cobalt– chrome, most with collars; cups mixed – metal-/ non-metal-backed; 2nd generation cement technique | (192) 131 (mean 7 years, range 5–12 years) | Mean 65 years, range 22–85 years | Johnston: pain none/mild 95%; walk satisfactory 84%; (other factors not specified). Cup mechanical failure rate 18.4%, including 9.6% revised (minimum 5-year follow-up). Stem mechanical failure rate 3.1%, including 2.3% revised. | 60% primary osteoarthritis. |
| Karrholm, <i>et al.,</i> 1994 Sweden A/B | Stem only – Lubinus SP I, plus cemented poly- ethylene cups | 58 primary (+ 26 revisions) (median 5 years 10 months, range 4 years 9 months– 7 years 10 months) | Median 68 years, range 41–83 years | Stem revisions, n = 9, $(10.7\%) - 7$ for thigh pain + radiographic loosening (but 6 were re-revisions) + 1 primary for osteolysis at 8 years. RSA of migration: logistic regression found migration at 2 years best predicto of failure (probable revisions > 50% if subsidence > 1.2 mm at 2 years). | Discusses other studies on failure prediction; percentages of revisions may mean results not applicable to primary THR. |
| Mohler, et <i>al.,</i> 1995 (a) USA Not rated | Stem only – Iowa Hip (Zimmer); mixture of cemented/non- cemented cups | 1941 (2–10 years) | (Mean 59 years – failed hips only) | I.5% (29) loose at mean of 5 years, I.1% revised. | Study of loosening/osteolysis. This type of failure not found in polished Charnley stems in study by same authors. |
| Ohlin, 1990 Sweden B | Christiansen | 265 (median 6 years) | Not specified | Radiographic survival at 10 years: stem 67%, cup 0%; 1/3 revised for aseptic loosening. | Abandoned design. |
| Ohlin & Onsten, 1990 Sweden B | Lubinus | 202 for survival; 151 for clinical follow-up (mean not specified, range 3–6 years) | Median 68 years, range 29–94 years | 3% revised for aseptic loosening (n = 3 cups, 2 stems, 2 both); 13% cups loose at 5 years; 10% stems loose at 5 years; clinical function not specified. | Hip dysplasia only factor associated with loosening; age < 65 years associated with higher rate of revision risk. |

DATA TABLE 4 Observational studies: cemented - non-Charnley

III

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|---|--|--|---|---|--|
| Oishi, et <i>al.,</i> 1994 USA B | Stem only – Harris Precoat; 3rd generation cemented technique | 100 88 for clinical follow-up (mean 7 years, range 6–8 years) | Mean 71 years, range 41–92 years | Harris score 91; 97% excellent/ good; thigh pain 3%. 1% (1) stem revision for loosening; no other loosening (0/81). | Good results attributed to cementing technique and precoating of prosthesis with cement to decrease risk of de-bonding; osteoarthritis 74%. |
| Partio, <i>et al.,</i> 1994 Finland A | Lubinus; traditional cemented technique; stem design changed to anatomic in 1982 | 444 (mean 10 years 2 months, range 8–12 years) | Mean 64 years | Total revision rate 11.5% (loosening plus technical error); estimated survival rate 87% at 10 years. Aseptic loosening: cup + stem 6.5%; stem only 2.5%; cup only 2.1%. No hip score reported. | Most frequently used cemented prosthesis in Finland; 71% osteo- arthritis; no significant differences for cup/stem survival, osteo- and rheumatoid arthritis, cup size, stem design, weight or gender groups; lower survival for age < 65 years. |
| Roberts, et <i>al.,</i> 1987 UK A | Howse | (506) 265 at 10 years 34 at 15 years (mean not specified, range 10–15 years) | Mean 63 years, range 19–89 years | 90% survival at 10 years; 80.8% survival at 15 years. 8.3% revised at 10 years; total revisions 54, 42 at < 10 years, 29 for aseptic loosening. Total failed including clinical/ radiographic 11.8%; revisions for aseptic loosening 4.35% at 10 years; revision for stem fracture 3.16% (especially in younger males). | Osteoarthritis 60%; senior + junior surgeons. |
| Rockborn & Olsson, 1993 Sweden B | Exeter; matt stem surface; 2nd generation cementation | (143) 110 radiographic/ clinical follow-up (minimum 5 years, mean not specified) | Mean 71 years, range 39–83 years | Charnley score: pain none/mild 78%. 5.6% revision rate (8/143 – 6 stems + 2 cups loose); radiographically, 21% definite/probable stem loosening, 3.6% cup loosening. | Osteoarthritis 78%; no association between loosening and age; poor stem results attributed to poor cementing and too large stem com- ponent; matt surface may prevent distal movement of stem within cement mantle. |
| Russotti, et <i>al.,</i> 1988 USA A | (Harris design); HD-2 stem; four common cemented cups | (251) (mean 5 years 6 months, range 5–7 years) | Mean 63 years, range 22–90 years | Harris score 97; 98% excellent. Stem loose (definite/probable/ possible) in 2.4%; cup migration, n = 1. | |
| Saito, 1992 Japan Not rated | Bioceramic; ceramic head/ UMWH cup | 57 (mean 6 years 2 months, range 5–8 years) | Mean 52 years 8 months, range 31–70 years | d'Aubigne total 16.6 (pain 5.7, walk 5.2, range of motion 5.7); 93% excellent/good. I revision at 6 years for stem loosening: no cup revisions, no ceramic head breaks; 7% (4) cups radiographic loosening, 3.5% (2) stems loose. | All osteoarthritis secondary to congenital dysplasia – high risk for cup failure. Wear not correlated with loosening but with calcar resorption. Authors suggest same bearing surface suitable for cementless implant in younger patients. Includes table comparing with three other prostheses. |
| Thomas, <i>et al.,</i> 1986 USA A/B | CAD; (minimum stress, maximum fix area; bulky rigid stem) | (114) 74 minimum 5 years follow-up (mean 7 years 1 month, range 5–10 years) | Mean 57 years, range 20–77 years | 9% (7) revisions, at 6–10 years (loose); survival 77% at 9 years (revisions) or 73.7% (revision + radiographic criteria). 87% unrevised excellent/good. | |
| Tompkins, et <i>al.,</i> 1994 USA A/B | Stem only – Triad (Johnson & Johnson); titanium stem, cobalt-chrome 28 mm head, collar | (142) 116 followed-up (mean 4 years 10 months, range 2–8 years) | Mean 63 years, range 18–88 years | Hospital for Special Surgery rating: mean 32.7; 92% excellent/good. Survival (loosening) 89% ± 3% at 4 years; 4.3% revision (done/pending). | Authors abandoned this design, quoting Russotti, 1988. Advise roughening or precoating of stem for cemented implant or choice of cobalt–chrome material; poor canal fill achieved in this series. Osteoarthritis 60%. |
| Warren, <i>et al.,</i> 1993 UK A/B | Furlong; straight stem; titanium alloy tapered in two planes | (195) 148 followed-up (mean 4 years 4 months, range 3–? years) | Mean 66 years | Harris score: 86. 6 year survival (revision) 97% (89.7–100%); 6 year survival (revised or loose) 79% (62.3–95.8%); (failures: 7 cups, 2 stems, 1 both). | All grades of staff undertook operations. Significant association between Harris scores and radiographic evaluations. |

DATA TABLE 4 contd Observational studies: cemented – non-Charnley

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|---|--|--|---|--|
| Bourne, et <i>al.,</i> 1994 Canada A/B | PCA; stem | 101 (5 years) Osteoarthritis only | Mean 61 years (range 26–81 years) | Harris score 90; thigh pain in 27% at 5 years. | No association between subsidence/thigh pain severity. |
| Cordero- Amuero, et al., 1994 Spain A/B | PCA, Howmedica; cup | 128; 113 reviewed (mean 5 years, range 4–8 years) | Mean 51 years (range 24–71 years) | 9 cup revisions; radiological: 40/75 neutral cups stable, 7/27 vertical cups. Fixation improved in 2 years in 12, worsened in 26. Harris score excellent/good in 85% (good in 61/64 stable cups, and 28/40 unstable cups). Bead loosening was progressive. | Uses Kaplan-Meier; teaching hospital; Hardinge's direct lateral. |
| Engh & Massin, 1989 USA B | AML; stem (+ cups) | 343; 204 for 5 years (mean 4 years 9 months) Subsets: (i) 200 with adequate fixation (canal-fill), mean follow-up 4 years 2 months; (ii) 143 without, mean follow-up 4 years 9 months | Means: (i) 58 years; (ii) 57 years | X-ray: 7% stems unstable at minimum 2 years postoperatively. Stable fix survival 94% at 5 years, 88% at 8 years. d'Aubigne-Postel:at 5 years: pain 5.7, walk 5.7, some thigh pain/limp in 9.4% patients. (i) mild pain 7.8%, moderate 0%; (ii) mild pain 20%, moderate 14.7%. Revision rate 4.4% (15, including 11 cemented cups for aseptic loosening, 3 stems, none for aseptic loosening). ** For subset < 55 years + no rheumatoid arthritis (n = 107), survival rate for stem fixation, 92% at 9 years (i.e. no difference from overall series). Combined mechanical failure rate, 6.4% at 5 years. | Attempts to control for suboptimal cup fixation in subgroup analysis. Statistically significant difference in survival canal-filling vs. under-sized stems. X-ray fixation and clinical results positively correlated. |
| Engh, 1993 USA C | AML, Dupuy; stem; (metal-backed porous-coated cups) | 393/227 (mean 8 years, range 1–13 years radiographically) | Not specified | Revision rate 4.4%; revision rate porous-coated stems 1.5%; stem revision rate for loosening 0.7% (3/393); 5/227 porous-coated cups revised (2.2%); revision rate for cemented cups 7.5% (11/166), survival 81.2% at 10 years; 11-year stem survival 91.8%. Overall failure rate include radio- graphic failures 10.8% (18/166). Revision rate later group: stems 0.5%, 9 year survival 99.3% (1/227); overall failure rate including radio- graphic 1.8%. | Author is originator of the AML system; reports on 2 models; hybrid subset reported. No clinical function results. |
| Engh, 1994 USA C | AML; stem | (226) 166 complete follow-up (mean 10 years) | Not specified | I revision – survival of 99.5% at 10 years. | Includes autopsy retrieval study. Osteo-integration stated in 98% if press-fit method correct. |
| Engh, et al., 1997 USA A/B | AML; stem (+ cup); (+ porous- coated AML cups) | (223) (minimum 10 years; 174 minimum 10-year evaluation, 137 10-year X-ray) | Mean 55 years (range 16–87 years) | Re-operation rate 11.5% (20/174) – 3 loose stems/symptomatic; 3 dis- locating cups; 4 cups loose/sympto- matic; 10 impending cup liner wear- through – + X-ray, 2 loose stems. At 12 years: total survival 85%; stem survival 97% (SE 0.02); cup survival 92% (SE 0.03), Clinical (n = 147, 10 years): pain – 87% none or slight, 10% with limiting pain; walk – 82% without aids; thigh pain – 8.5%, 4% limiting. | Authors claim stem revision rate comparable to Charnley at 10 years (mean age 57 years) and 16 years (mean age 42 years) (cf. Sullivan, et al., 1994). Patients with re-operation and/or osteolysis significantly younger than others. All loose stems were 'undersized'. |

DATA TABLE 5 Observational studies: cementless - porous-coated (some hybrid with porous-coated acetabular components)

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| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|---|--|--|--|---|
| Heekin, et <i>al.,</i> 1993 USA A/B | PCA; stem + cup | 100 (5–7 years) | Mean 58 years (range 22–81 years) | Harris score 92 (5 years): survival 93% (at 5 years) with end-point cup migration/stem subsidence. Survival 98% revision-only end-point; revision rate 2%; stem subsidence 5%; pain – none/slight 75%; thigh pain increasing 18–26% in years 1–4, decreasing to 16% in year 7. | Detailed radiographic results; multivariable analysis of clinical vs. radiographic results. |
| Hellman, <i>et al.,</i> 1997 USA B | Omnifit (Osteonics) cobalt-chrome; stems (mostly + cementless cups) | 111; 79 reviewed (analysis suggests representativeness) > 5 years (mean 8 years 5 months, range 5 years 4 months- 10 years 5 months) | Mean 45 years (range 19–71 years) | 5.1% (4) stem revisions – 2.5% (2) for aseptic loosening. Pain: 96% none or slight, 4% moderate; limp: none or slight, 97.3%. Radiographic (n = 72): 70 stable (97.2%) with signs of bone ingrowth; osteolysis 12% (9) treated by bone grafting (thus total mechanical failure rate, 3.8% (3)). Survival free of aseptic loosening at 10 years 91.3% (\pm 5.7%). | Osteolysis possibly related to polyethylene thickness; discusses other prostheses evidence for osteolysis. |
| Holman & Tyer, 1992 Australia B/C | PCA; stem + cup | 318 (1–6 years; mean not specified) | Mean 53 years (range 17–71 years) | Revisions: 1% (3) – 2 undersized stems, 1 cup loosening at 3 years in rheumatoid arthritis patient. Harrington ARS 100-point (pain/ function/gait/motion/deformity): good/excellent 80%; 13% some thigh pain. | |
| Incavo, et <i>al.,</i> 1993 USA B | Harris-Galante and Optifix; cup | 106 Harris-Galante 66; Optifix 40 (minimum 2 years, range 2–4 years 4 months) | Harris-Galante, mean 63 years; Optifix, mean 61 years | 2 Harris-Galante cups revised, I migration, I dislocation; no other loosening. (No function measures) | No statistical correlation with migration/radiolucency of: age, sex, cup coverage, component inclination, number of fixing screws |
| Jansson & Refior, 1992 Germany B/C | PCA; stem (+ screw cups) | 81 (mean 2 years 5 months, range 1 year 2 months- 3 years 4 months) | Mean 56 years | l revision; d'Aubigne score mean 13.6. | Includes patient satisfaction (7 not satisfied); X-ray results counter theory of osseo- integration. |
| Kienapfel, <i>et al.,</i> 1991 Germany B | BIAS; stem, modular (cup Harris-Galante) | | Mean 50 years | Mean Harris score 90.7% at 2 years (good/excellent 91.6%). Radiographic: 95% stable; no cup migrations. | Small sample, short follow-up; no statistically significant differences in clinical results between stable/ unstable groups; various surgical approaches. |
| Kim & Kim, 1992 South Korea B/C | Harris-Galante; stem (+ cup) | 82 (mean 5 years 2 months, range 5–5 years 6 months) | Mean 52 years (range 24–86 years) | Harris score, 83; 62% excellent/good. 10% stems loose (revised or to be revised); 28% (20) thigh pain in non- loose stems. Radiolucency > 2 mm in 33%. | |
| Kim & Kim, 1993 South Korea A/B | PCA; stem + cup | 116 (6 years 1 month– 7 years 5 months) | Mean 48 years (range 19–85 years) | Harris score 91 (latest); 88% excellent/good at 6 years. 3 cups loose (+ 20 excessively worn liners); 7 stems loose; osteolysis in 33%. 17% with good stem fit had thigh pain (17/98), 9% persistent thigh pain (7/9 stems – loose-fit). | Wear related to young age but not weight, sex, diagnosis, hip score, hip movement. |
| Lachiewicz, 1994 USA B/C | Harris-Galante, titanium alloy; stem + cup (both coated, some screw-fix) | 35 (mean 4 years 5 months, range 3 years–6 years 5 months) | < 60 years; mean 41 years (range 18–59 years) | Harris score, mean 91; 81% good/excellent. No revisions for aseptic loosening. X-ray: I definite cup loose; 3 stems non-progressively loose. | Medication recorded; rheumatoid arthritis patients. |

DATA TABLE 5 contd Observational studies: cementless – porous-coated (some hybrid with porous-coated acetabular components)

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|---|---|---|---|--|
| Learmonth, et al., 1995 South Africa A/B | PCA; stems | 104 (mean 4 years 2 months, range 2 years-6 years 5 months) | Mean 43.4 years (range 16–67 years) | d'Aubigne score, 94% clinically excellent; thigh pain 23% (severe in 2); revision rate 1.9% (2, both loose). | Comments on osteolysis, radiographic results. |
| Maloney, et <i>al.,</i> 1992 USA C | ARC, Howmedica; cup – beaded, screw-fix (+ cemented stems), i.e. hybrid | 56 (mean 4 years 7 months) | Not specified | 19.6% bead loosening (increasing over time), I associated with migratio I with broken screw. | n, |
| Moskal, et <i>al.,</i> 1994 USA B/C | PCA; stems (+ uncemented peg-fix PCA cups) | 100 (2-4 years) | Mean 63 years (range 27–95 years) (no previous arthroplasty in followed-up group) | Harris score at 2 years, 90; thigh pain 5% at 3 years; limp in 18% (believed unrelated to prosthesis or surgical approach); 99% stable. | Conducted in community hospital; compared porous-coated to hybrid (n = 34): no statistically significant differences (in spite of mean age in hybrid group being 12 years greater). Stem head larger than used conventionally – attributed with good early results by authors. |
| Negre & Henry, 1995 France B | TA6V (authors' model); stem + cup, blasted titanium with press-fit cup | 101 (6 years) | Mean 68 years (range 30–88 years) | d'Aubigne clinical: 94% 'perfect', 4% mild pain; 2 revisions for ceramic head fracture; 2 stem migrations, 3 stems loose due to poor intramedullary fit. | Theory of the design is to allow bone-ingrowth without fibrous layer between bone-metal. |
| Owen, <i>et al.</i> , 1994 UK A | PCA (Howmedica) | 241 (mean 5 years, range 2–9 years) | Mean 47 years (range 18–65 years) | Overall survival (for recommendation for revision) 91% at 6 years (\pm 6%); 73% at 7 years (\pm 11%); 57% at 9 years (\pm 20%). 6 cup failures due to loosening in 6 years; 6 stem failures in total (one intraoperative fracture) at mean of 4 years (all had poor original intramedullary fit). Osteolysis in 36% cups (n = 99) surviving > 5 years, 13% in stems. Subsidence 4% in stems > 5 years. | Analysis with CIs. Mean age at revision 39 years; cup failure at mean of 6 years; 20/26 have widespread osteolysis; all had loose beads + excessive poly- ethylene wear; 12 had migrated. Low overall survival caused by huge decline in survival of cups in years 6-9: 30% (n = 95) attributed to severe polyethylene wear (large head size, 32 mm was used), osteolysis and migration. Mixed surgeons; specialist centre; lateral without trochanteric osteotomy. |
| Pellegrini, et <i>al.,</i> 1992 USA B | Tri-lock; stem, beaded | 57; 51 reviewed (mean 6 years 5 months, range 5–8 years) | Mean 49 years | Harris score 84%, good/excellent; Mayo 70% good/excellent; excluding hips with previous major procedures; Harris score, 88% good/excellent. I revision for aseptic loosening, I for persistent pain; subsidence in 2 stems, I > 5 mm. | Small sample size; cobalt-chrome; long follow-up for beaded; patients selected for high-risk early failure cemented implant. Poorest results in hips with previous procedures. |
| Schmalzried & Harris, 1992 USA B | Harris-Galante; cup (screw-fix) | III cups; 83 reviewed (mean 5 years 8 months, range 5–7 years) | Mean 59 years (range 23–79 years) | Harris score: mean 93 (73–100). No cup loosening, 4 cup revisions – 2 liners detached, 1 metallosis, 1 lysis. No continuous radiolucent line around whole cup. | Comparison of cemented (n = 40) vs. non-cemented (43), porous- coated stems: Harris scores 95 vs. 92 - caused by pain scores 43 cemented vs. 40 non-cemented; i.e. hybrid marginally better than non- cemented/non-cemented. Senior surgeon. |
| Shaw, et <i>al.</i> , 1992 USA B | AML; stem (bipolar cups) | 178; 154 for analysis of which 122 complete (mean 3 years 4 months, minimum 2 years) | Mean 57 years 7 months | 92.3% stable; 9% postoperative groin pain. Harris score: 84. | Patient satisfaction; no relationship age/Harris score; no relationship sex/type of stabilisation. |
| Sotereanos, et al., 1995 USA B | Two series: (supplied separately) (i) BIAS; (ii) AML; stems (i) + cemented cup (ii) + porous-coated cup | 2 months, range 7–15 years (ii) mean 8 years | (i) mean 53 years (ii) mean 53 years 8 months | (i) 5 (4.1%) revisions at mean of 10 years 2 months (2 for late loosening); survival 95.4% at 11 years (13 cup revisions). (ii) 1 (0.6%) stem revised for loosening, 99.3% survival at 9 years. 94.6% pain-free at last follow-up; 3 stems X-rayed unstable, 2 significant osteoly | Patient satisfaction also measured. Pro-cobalt–chrome. sis. |

DATA TABLE 5 contd Observational studies: cementless – porous-coated (some hybrid with porous-coated acetabular components)

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| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|---|---------------------------------|---|---|--|--|
| Tang-Kue, 1995 Japan Not rated (abstract only available) | PCA; stems and cups (2-peg fix) | 119 (mean 7 years) | Mean 46 years (range 19– 78 years) | Harris score: 95; 92.4 excellent/ good; 24.4% slight or > pain walking; 5.9% considered unstable; no revisions. | |
| Xenos, <i>et al.</i> , 1995 USA B | PCA; stems and cups | 100 (minimum 7 years) | Mean 58 years (range 22– 81 months) | Harris score: 92.4. 5% total revision – 2% stem, 3% cup; osteolysis around stem in 11%, cup in 2%, both in 2%. Most patients with osteolysis asymptomatic. | Osteolysis study: osteolysis occurred frequently around components with no evidence of migration/subsidence; mean age of osteolytic group younger by 10 years than others. |

DATA TABLE 5 contd Observational studies: cementless – porous-coated (some hybrid with porous-coated acetabular components)

DATA TABLE 6 Observational studies: cementless – HA-coated

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|--|---|--|---|--|
| Capello, 1994 USA C | Osteonics; stem | (436) 151 for 5 years | Mean 50 years | Harris score, 95: pain, 93% none/ slight; thigh pain, 1.3% mild/moderate. Subsidence > 3 mm, n = 2; revisions, n = 10 (5 for pain, aseptic loosening); none loose. Total mechanical failure, 0.46% (excl. pain). | Multicentre |
| d'Antonio, et <i>al.,</i> 1992a USA A | Omnifit (Osteonics); stem | (238) (92 for minimum 2 years) | Mean 48 years | Harris score, 95 at 2 years; pain, 5% mild to moderate. Revisions, 2/238 (0.8% within 2 years). | Presumably earlier set from same series as previous study. Patients stated to be more active and heavier than in most comparable studies. Similar cup comparison results as for study above (23 HA-, 69 porous-coated). 5 centres |
| d'Antonio, et <i>al.,</i> I 992b USA A/B | Osteonics; stem and cup | 320 (minimum 2 years); 142 (minimum 3 years) | Mean 50 years | Harris score, 95 at 3 years; pain, 4.2% mild to moderate, thigh pain, 1.4%. No revisions; stems – aseptic loosening 2, X-ray unstable 0, total 0.46%; cups – 1% migration at 2 years. | Comparison of HA- (132) vs. porous- coated ingrowth (285) cups showed no statistically significant difference in clinical Harris scores at any time up to 3 years. Multicentre |
| Drucker, et al., 1991 USA C | No model name, authors' experi- mental design; stem and cup | | Mean 53 years, range 22– 73 years | Not specified | |
| Geesink, 1990 The Netherlands A/B | Omnifit (Osteonics); stem and cup | 100 (85 primary reviewed) (1 year 5 months- 3 years 3 months, mean 2 years) | Mean 54 years, range 21– 74 years | Harris score, 97; persisting pain 4%. No loosening. Harris score by cup type: HA-coated 98 vs. non-coated 94 (but at 3 months 90 vs. 71; at 6 months 95 vs. 79). | Harris cup score comparisons. HA-coated vs. non-coated contradicts d'Antonio, <i>et al.</i> , 1992b study. |
| Geesink & Hoefnagels, 1995 The Netherlands A | | 118 stems; 100 cups, threaded design only (5 years 6 months– 7 years 6 months) | Mean 53 years, range 21– 65 years (31 patients < 50 years) | Survival: stem 100%, cup 99%. Harris score: at 3 months 90, at 6 years 98. d'Aubigne: at 6 years – pain 5.8; motion 5.9; walk 5.9 (total 17.6). Persisting pain 4%; no osteolysis. | No association of age, gender, surgeon or weight with Harris scores at any period. Harris scores compare with < 90 for most porous and press-fit series, author claims. Notable early pain relief. |
| Koch, <i>et al.,</i> 1993 Germany B? | Furlong | 233 (190 primary) (2–5 years, mean 2 years 9 months) | Not specified | No aseptic loosening; no thigh pain. d'Aubigne: 15.76. | In German. |
| Rossi, et <i>al.,</i> 1995 Italy A/B | ABG Howmedica; stem and cup | 100 (minimum 2 years) | Mean 63 years | d'Aubigne: 100% excellent/good. 0% mechanical failure (1 dislocation due to cup malpositioning). No cup migration; postoperative bone- cup gaps disappeared in 3–12 months. | More details of radiographic findings given |
| Tonino, et al., 1995 International (Europe) A/B | ABG, Howmedica; stem and cup | 222 (minimum 2 years, mean 2 years 4 months) | Mean 62 years 7 months | 3.6% thigh pain. 4 early + 3 late dislocations (total, 3%; 2-year mechanical revision rate, 1.4%). Activity: preoperative 14.9%, at 2 years 87.3%. d'Aubigne: mean 17.4 (max. 18). Minor stem migration in 6 (2.7%); normal bone adjacent to cup in 95%. | International study; 10 surgeons; all dislocations from same single centre. No influence on clinical scores of age, weight, gender, disease, Charnley classification. No statistical correlation between radiographic results and clinical scores. Very detailed radiographic analysis. |

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|--|---|---|--|---|--|
| Blaha, et <i>al.</i> , 1994 USA C | CLS stem (Protek, Switzerland); collarless, tapered wedge, grooved, rough-blasted surface | 300 (minimum 5 years) | Not specified | Revision rate for mechanical loosening: 1.7% (5 – 2 cup/ 2 stem, I fractured ceramic head) + radiographic loosening of 2 stems (total mechanical loosening rate for stem, 1.6%). Pain: 89% none/slight; Harris score > 85 (89%); thigh pain 1.3% (4). | Author claims results as good as for porous-coated stems. Poorly reported but evaluation was by independent observers. |
| Duparc & Massin, 1992 France B/C | Bichat 3 stem (Howmedica); smooth, fluted titanium | (203) 2 years: clinical 157; radiographic 145 (46 for 4 years, maximum 6 years) | Mean 57 years (range 18–85 years) | 32 revised; survival 77% at 6 years (revision end-point). d'Aubigne: at 2 years 89% excellent/ good (non-revised). | Indications: use of this design now restricted to patients in whom cement is contraindicated by history of previous infection or very young age. |
| Glorion, et al., 1994 France A/B | Osteal cup (Ceraver), polyethylene screwed; stem: cemented, 32 mm head | 77 (mean 3 years 6 months, range 1–7 years) | Mean 63 years (range 25–76 years) | Migration-free survival 74.5% at 9 years; revision-free survival 92%. Abandoned. | All osteoarthritis. |
| Harper, et <i>a</i> l., 1995 UK B | Ring UPM cup; wedge press-fit plus Ring uncemented stems (87) or Norwich cemented stems (39) | 126 (mean 4 years 5 months, range 1–7 years 6 months; 59 for mean 6 years 5 months) | Mean 63 years (range 31–93 years) | (Total revisions 22%); 17% revised for loosening. Survival 83% (76.8-89.2) at 8 years. No function data given. Polyethylene press-fit concept abandoned. | Life-table survival analysis. Mean time to granulomatous loosening 5 years 3 months; failure attributed to polyethylene wear. Results compared with other studies of Ring prostheses. |
| Kennedy, 1994 USA C | Arthrophor I cup (Joint Medical Products); press-fit (screw/peg-free, metal-backed) | 488 (most 3–6 years, minimum 2, maximum 8 years) | Not specified | No revisions for loosening. Osteolysis in 3.1%; loose beads in 3%. | Press-fit interface of 1.5 mm, reamed exactly; author attributes success to this. |
| Kutschera, et <i>al.,</i> 1993 Austria Not rated | Zweymuller peg-free stem | 96 (mean 5 years 3 months, range 5–5 years 9 months) | Mean 67 years 3 months (range 41–87 years) | Mean Harris score: 87.5. I cup revised for aseptic loosening; no stem revisions; I stem subsidence of 4 mm. | Abstract only. |
| Seral, <i>et al.</i> , 1992 Spain B/C | Zweymuller peg-free stem; cup: Endler polyethylene threaded | 260 (mean 5 years, range 1 -6 years) | 69% 50–70 years (8%, 70+ years) | Singh: 67% very good/good. Cup migration, 17.6%; stem subsidence > 4 mm, 27%. Osteoarthritis group (152): 78.5% very good. No revisions reported. | |
| Stockley, et al., 1992 Canada B | Müller straight stem; designed for cementing | 24 (mean 7 years 3 months, range 6 years 2 months– 8 years 3 months) | Mean 61 years (range 46–77 years) | Harris score: mean 79. 5 revised for aseptic loosening, 1 failed clinically. Survival 80% at 8 years. | Very small sample. Pre-dates porous coating (1982–84). Authors recommend titanium rather than cobalt–chrome. |
| Wilson- MacDonald, et al., 1990 Switzerland B | RM cup: pegged polyethylene, some screw-fixed; isoelastic; plus Müller cemented stem | 445 (5-10 years) | Mean 65 years (range 29–89 years) | d'Aubigne: 86% excellent/good. Revisions for aseptic loosening, n = 32, most > 8 years; about 28% radiologically loose at 9 years. Abandoned. | Good results up to 6 years. Smaller cups and use of screws associated with more loosening; increased wear in younger patients. "Bone/polyethylene contact should be avoided." |

DATA TABLE 7 Observational studies: cementless – uncoated press-fit

DATA TABLE 8 Observational studies: hybrid

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|---|--|--|--|---|--|
| Harris & Maloney, 1989 USA B | ARC cup, n = 52, HD-2 stem (Howmedica); Harris-Galante cup/Precoat, n = 74, (Zimmer) stem | 126 (mean 3 years 6 months, range 2–5 years 7 months) | Mean 63 years (range 23–83 years) | Harris score: 93. No revisions for loosening. | Harris Galante/Precoat better than ARC HD-2 clinically. Single senior surgeon. |
| Helfen, et al., 1993 Germany Not rated | Marburg porous- coated cup; nails plus peg; titanium stem | 212 (3–6 years) | Mean 60 years (range 33–76 years) | 96% very good/good. I revision for loosening. | Abstract only. |
| Kienapfel, et <i>al.</i> , 1992 Germany B | Harris-Galante porous-coated cup; Griss stem (Sulzer AG), titanium with ceramic head | (40) 33 followed-up (mean 3 years 3 months, range 2 years 10 months- 5 years) | Mean 55 years (range 32–70 years) - | Pain: 16% mild to moderate (most post hard activity); limp slight to moderate in 24%. I cup possibly unstable; no revisions. | |
| Mohler, et <i>al.,</i> 1995 USA A/B | Harris-Galante cup and stem; porous- coated cup, screw-fix | I53 I20 clinical review I09 X-ray (mean 5 years 2 months, range 4 years–7 years I month) | Mean 67 years (range 39–85 years) | Harris score: 86 (90 after excluding patients with unrelated problems). Pain: none, slight, mild in 97%. No revisions; 2% (2) definite stem loosening; 2% (2) definite cup loosening, others stable. Survival 95% (95–100) at 7 years I month (cup 98.5%, stem 96.6%). | Authors support hybrid for older patients. 4 senior surgeons plus assistants. |
| Pearse, et al., 1992 UK B/C | Harris-Galante porous-coated screwed cups; Müller straight cobalt chrome stems | 58 (mean 3 years 6 months, range 2 years 6 months- 5 years 6 months) | Mean 53 years 5 months (range 28–82 years) | Harris score: 91; 91% excellent/ good. I stem revision for loosening (in patient with previous cemented THRs). No stem migration; I cup progressive radiolucency, no cup migration. | |
| Schmalzried & Harris, 1993 USA B | Comparison of: (i) ARC cup, HD-2 stem (Howmedica) (ii) Harris-Galante cup, Harris Precoat stem (Zimmer) Both stems collared; both cups screw-fixed | (101) 97 followed up (i) 52; (ii) 49 (mean 6 years 5 months, range 5–8 years) | Mean 61 years (range 23-83 years) | Harris score: 93; 91% good/ excellent. 90% no or slight pain; Pain less for Harris-Galante group (statistically significant). I revision for stem loosening – in a custom component; no stems loose; no Harris-Galante cup loose or revised for loosening; I Harris-Galante cup revised for liner failure. 2 ARC cups migrated; no cup revisions for loosening. Osteolysis in 2 ARC cups, none in Harris-Galantes. | Harris score slightly better for Harris-Galante/Precoat group. Bead loosening, etc., reported. |

| Study, country, rating | Prosthesis type | Number followed-up (duration of follow-up) | Age | Outcome measures; results | Notes/comments |
|---|--|---|--------------------------------------|--|--|
| Lautiainen, et al., 1994 B/C | Two macro- interlock designs (i) Lord Madreporic (ii) Link | (i) 49 (ii) 20 (mean 5 years 4 months, range 4 years 9 months- 7 years 7 months) | Mean 58 years (range 36–76 years) | Mayo: 86.7; 78% good. Total revision rate 6.3%. | No correlation between radiographic and clinical ratings. |
| Niinimaki, et <i>al.</i> , 1994 Finland B | RM; stem only; macro-interlock | (114) 85 71 SSTRR questionnaire/ radiographic (7–9 years) | Mean 64 years (range 48–79 years) | Harris score: 43% excellent/good; Johnston: 67% pain none/slight. Revisions for loosening, n = 8, plus I fracture; total mechanical failure rate, 10.6%. Radiographic failure 25%; subsidence > 5 mm in 12%; osteolysis in 12%. | Osteoarthritis only. |
| Riska, 1993 Not rated | Ceraver Osteal hybrid/ceramic 2 series, cemented and uncemented cups | 112 (mean 3 years 6 months, range 1–7 years) | Mean 62 years | Revision rate, 7% for uncemented cup; 1.7% revisions for aseptic loosening. | |
| Roffman & Juhn, 1993 Israel C | RM (Mathys, Switzerland); cup only; (isoelastic) (i) HMHDPE (ii) ditto HA-coated (iii) ditto titanium- coated | 185 (i) 60 (ii) 96 (iii) 29 (9 years) | Not specified | No hip scores. Total revisions, 2.7% (n = 5), all in (i) (8.3% of group); none in (ii) and (iii). Migration, de-alignment or pain in same, 2.7%. | Good ingrowth in groups (ii) and (iii). |
| Stern, et al., 1992 C | LD; some HA-coated, some roughened | 112 (6 months– 2 years; 60 for up to 2 years) | Mean 62 years | d'Aubigne: 86% excellent/good; pain 5.6%; limp 12%. Number loose not specified. 'Low' stress shielding. | Complex radiographic analysis. |

DATA TABLE 9 Observational studies: cementless - mixed types

DATA TABLE 10 Observational studies: cementless – threaded cups (A sample of studies, not critically appraised; this design is now largely abandoned.)

| Study, country | Number followed-up (duration of follow-up) | Outcome measures, results |
|---|---|--|
| Bruijn, <i>et al.</i> , 1995 The Netherlands | 411 (mean 4 years 6 months, range 3–7 years) | Clinical: 82% excellent/good. Migration 25%; 6% revised for aseptic loosening. Abandoned. |
| Fox, et <i>al.,</i> 1994 Canada | 68 (mean 6 years, range 5–9 years) | 38% failure; 17 revisions at mean of 5 years. Abandoned. |
| Gouin, <i>et al.,</i> 1993 France | 107 (2-5 years) | Survival 75% at 5 years; revision rate 11.6%. d'Aubigne: excellent/very good/good, 62%. Abandoned. |
| Gut, et <i>al.</i> , 1990 Switzerland | 102 (5-7 years) | 33% sockets loose. |
| Harwin, et <i>al.,</i> 1991 USA | 62 (mean 2 years 4 months) | 8% re-operation, 10% failures including loosening. |
| Krugluger & Eyb, 1993 Austria | 103 (minimum 10 years) | Revision rate 24% for loosening; loosening 33%; extensive osteolysis 31%. 5-year results had been good. |

Appraisal Table I – RCTs

Key criteria

1. Method of randomisation identified and appropriate. 2. Patient groups balanced or effect of any difference evaluated in valid statistical analysis. 3. Patients blind to prosthesis type. 4. Assessments of clinical/radiological outcome blind to prosthesis type if possible. 5. Appropriate statistical analysis. 6. Number of patients deceased or lost to follow-up reported or included in statistical analysis. 7. Follow-up period – mean and range. 8. Prosthesis model specified. 9. Clearly defined criteria for measuring outcomes. 10. Age – mean and range.

Other criteria

11. Quantification of outcomes. 12. Follow-up data compared with preoperative data (preferably mean and range). 13. Independence of investigators (declared or no vested interest). 14. Numbers of men and women given. 15. Weight – mean and range. 16. Preoperative diagnoses with percentages/numbers of patients given. 17. Clinical evaluation independent of operating surgeon.

| | | | Key c | riteria | | | | | | | Ot | her cri | teria | | | | | |
|--|---|----|-------|---------|----|---|---|---|---|----|----------------|---------|-------|----|----|----|----|-------|
| Study | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | Ratin |
| Bourne, et <i>al.,</i> 1995 ^a Rorabeck, et <i>al.,</i> 1996 ^a | n | У | У | у/у | NS | у | у | у | у | у | y ^a | у | у | у | n | у | у | с |
| Bradley & Lee, 1992 | у | NS | NS | NS | NS | у | у | у | n | у | n | n | NS | n | n | у | у | С |
| Carlsson, et al., 1995 | n | NS | NS | NS | у | n | у | у | у | n | у | n | NS | n | n | n | NS | с |
| Ciccotti, et <i>al.,</i> 1994 | n | у | NS | NS | у | у | у | у | у | у | n | у | NS | n | у | у | NS | с |
| Godsiff, et <i>al.,</i> 1992 | у | у | у | y/NA | у | у | у | у | у | у | у | n | NS | у | n | у | у | A |
| Jacobsson, et al., 1994 [*] | n | у | NS | NS | n | у | у | у | у | у | у | n | NS | у | n | n | NS | с |
| Karrholm, et al., 1994 | у | у | NS | NS | у | n | у | у | у | у | у | у | у | у | у | у | n | с |
| Kelley, et al., 1993 | n | у | NS | NS | у | у | у | у | у | у | у | n | NS | у | у | у | NS | с |
| Krismer, et <i>al.,</i> 1994 | n | у | NS | NS | у | у | у | у | у | у | у | n | NS | у | n | у | NS | с |
| Marston, et <i>al.,</i> 1996 | у | NS | NS | NS | NS | у | у | у | у | у | у | у | у | у | n | у | у | с |
| Olsson, et <i>al.,</i> 1986 | n | у | NS | NS | n | у | у | у | у | у | у | у | NS | у | у | у | NS | с |
| Onsten & Carlsson, 1994 | n | у | NS | NS | у | у | у | у | у | у | у | n | у | у | у | у | NS | с |
| Onsten, et <i>al.,</i> 1994 | У | у | NS | NS | у | у | у | у | у | у | у | n | NS | у | у | у | NS | с |
| Reigstad, et <i>al.,</i> 1986 | n | у | NS | NS | n | у | у | у | у | у | у | у | NS | у | у | n | NS | с |
| Søballe, et <i>al.,</i> 1993 | n | NS | NS | NS/y | у | у | у | у | у | у | у | у | у | n | у | у | NS | с |
| Thanner, et <i>al.,</i> 1995 [*] | n | NS | NS | NS | n | у | у | у | у | у | у | у | NS | у | n | у | NS | с |
| Wykman, et <i>al.,</i> 1991 | n | У | NS | NS | NS | у | у | у | у | у | у | у | у | у | У | у | NS | с |

^a Same study group. Bourne, et al., 1995: clinical data 5-year follow-up; Rorabeck, et al., 1996: radiographic data 4-year follow-up.

Appraisal Table 2 – Non-controlled comparative studies

Key criteria

1. Method of assignment of patients to different prostheses described and appropriate. 2. Patients matched or differences evaluated in valid statistical analysis. 3. Appropriate statistical analysis undertaken. 4. Number of patients deceased or lost to follow-up reported or included in analysis. 5. Follow-up period, range and mean specified. 6. Prosthesis models specified. 7. Clearly defined criteria for measuring outcomes. 8. Age - mean and range.

Other criteria

9. If retrospective, patients selected without knowledge of outcomes. 10. In prospective studies, followup assessments blind to prosthesis type, if possible. 11. Results given for specific models (and sizes). 12. Quantification of outcome criteria. 13. Follow-up data compared with preoperative data (mean and range). 14. Independence of investigators (declared or no vested interest). 15. Numbers of men and women given. 16. Weight - mean and range. 17. Preoperative diagnoses with percentages/numbers of patients given. 18. Clinical evaluation independent of operating surgeon. 19. Radiological evaluation independent and blinded to clinical results.

| | | | I | Key cr | iteria | | | | | | | | Ot | her cri | iteria | | | | | |
|--|---|----|----|--------|--------|----------------|---|---|----|----|----------------|-----|----|---------|--------|----|----|----|----|--------|
| Study | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | Rating |
| Abrahams & Crothers, 1992 | n | n | у | n | у | n | у | у | | NS | y ^a | У | n | NS | у | n | У | NS | NS | с |
| Ahnfelt, et al., 1990 | n | n | у | n | n | n | n | n | n | | n | n | n | NS | у | n | у | NA | NA | с |
| Bankston, et <i>al.,</i> 1993 | у | у | у | n | у | У | у | У | у | | У | У | n | NS | у | у | n | NA | NS | с |
| Bankston, et <i>al.,</i> 1995 | у | у | NS | n | у | у | у | у | у | | у | у | n | NS | у | у | n | NA | NS | с |
| Bertin, et al., 1985 | n | n | NS | у | у | у ^ь | n | n | | NA | n | у | n | NS | у | n | у | NS | NS | с |
| Britton, et al., 1996 | n | NS | у | у | у | у | у | n | | n | у | n | n | у | n | n | n | n | n | с |
| Burkart, et <i>al.,</i> 1993 ^c | у | n | У | У | у | У | у | У | | у | У | У | n | NS | у | n | У | NS | У | с |
| Callaghan, et <i>al.,</i> 1995 | n | n | n | n | n | У | У | n | NS | | y/n | y/n | n | у | n | n | n | NS | NS | с |
| Carlsson & Gentz, 1982 | n | n | NA | у | у | у | у | n | n | | n | У | n | NS | n | n | n | NS | У | с |
| Chmell, et al., 1995 | у | n | NS | n | n | у | n | n | NS | | у | n | n | NS | n | n | n | NS | NS | с |
| Cornell & Ranawat, 1986 [*] | у | у | NS | у | у | у | у | у | у | | n | У | n | NS | у | у | у | NS | У | с |
| Dall, et <i>al.,</i> 1993 [*] | у | n | n | у | у | у | у | у | у | | у | у | n | у | у | n | у | NS | NS | с |
| Duck & Mylod, 1992 | n | n | NS | n | у | n | у | у | NS | | n | n | n | NS | у | n | у | NS | NS | с |
| Ebramzadeh, et <i>al.,</i> 1994 | у | NA | у | у | у | у | у | n | у | | n | У | n | у | у | n | У | NA | У | с |
| Espehaug, <i>et al.</i> , 1995 | n | n | у | у | у | у | у | n | у | | у | У | n | NS | у | n | n | NA | NA | с |
| Freeman & Plante- Bordeneuve, 1994 | n | n | у | n | n | n | у | у | | NS | y ^a | у | n | у | у | n | у | у | NS | с |
| Goetz, et al., 1994 | у | у | NS | n | у | у | у | у | у | | у | у | у | у | n | у | у | NS | NS | с |

[®] Studies not comparing typical prostheses.

^a Results given for type of prosthesis, not specific model.

^b Unclear if the prostheses used in this study were/are now in widespread use or designed for this study only. ^c Appraisal covers new data given in Burkart, et al., 1993⁹⁹ only. Bourne, et al., 1994 is appraised in Appraisal Table 5.

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continued

| | | | | Key cr | iteria | | | | | | | | Ot | her cri | teria | | | | | |
|---|----|----------------|----|------------------|--------|------------------|---|---|----|----|----------------|----|----------------|---------|-------|----|------------------|----|----|--------|
| Study | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | Rating |
| Hamada, et <i>al.,</i> 1993 | У | n | n | n | у | У | у | У | У | | У | У | n | NS | у | n | У | NS | NS | С |
| Havelin, et al., 1994 | n | n | у | у | у | n | у | У | У | | n | У | n | NS | у | n | n | NA | NA | С |
| Havelin, et <i>al.,</i> 1995 | n | n | У | у | у | У | у | у | У | | У | У | n | NS | у | n | У | NA | NA | С |
| Hearn, et <i>al.,</i> 1995 | У | n ^d | у | у | у | У | у | у | У | | n | у | у | NS | у | n | У | у | NS | С |
| Hedlundh & Fredin, 1995 [*] | n | у | у | у | n | У | у | у | n | | У | n | n | NS | у | n | У | NS | NA | с |
| Hernandez, et al., 1994 | n | у | у | n | n | У | у | n | У | | У | У | n | у | n | n | У | NS | NS | с |
| Hodgkinson, et al., 1993 | n | у | У | у | у | У | n | У | У | | У | У | n | NS | у | У | У | NS | NS | С |
| Hoffman, et <i>al.,</i> 1994 | n | n | У | у | n | У | у | У | У | | ye | n | n | NS | у | n | У | NS | NA | С |
| Horikoshi, et <i>al.,</i> 1994 | n | n | NS | n | у | У | у | у | n | | n | У | n | NS | у | n | У | NS | NS | С |
| Hozack, et <i>al.,</i> 1993 | n | n | у | n | у | У | у | у | | NS | У | У | У | NS | у | у | У | NS | NS | С |
| Hozack, et al., 1994 | n | у | у | y/n ^f | у | y/n ^f | у | У | NS | NS | n | У | У | NS | у | У | y/n ^f | NS | NS | С |
| Huracek & Spirig, 1994 | у | у | у | у | у | У | n | У | у | | У | У | n ^g | NS | у | n | У | У | NS | с |
| Hwang & Park, 1995 | n | n | n | у | у | У | у | у | | NS | у | у | у | NS | у | n | у | NS | NS | с |
| Jacobsson, et <i>al.,</i> 1990 | n | n | у | у | у | у | у | у | | NS | n | у | n | NS | у | у | n | NS | NS | с |
| Kelley & Johnstone, 1992 [*] | у | у | у | у | у | у | у | у | у | | у ^h | у | n | NS | у | n | у | NA | У | А |
| Krismer, et <i>a</i> l., 1991a | n | n | у | у | у | У | у | у | у | | у | у | n | NS | у | n | У | NS | NS | с |
| Krismer, et <i>al.,</i> 1991b | n | n | у | у | у | У | у | у | у | | у | у | n | NS | у | n | у | NS | NS | с |
| Kristiansen & Steen Jensen, 1985 [*] | NA | у | у | n | у | У | у | у | n | | у | у | n | NS | у | у | У | NA | NS | В |
| Lehman, et <i>al.,</i> 1994 [*] | у | у | у | у | у | У | у | у | у | | n ⁱ | у | у | у | у | у | у | NS | NS | А |
| Mallory, et <i>al.,</i> 1989 [*] | у | у | у | у | n | У | у | у | n | | n | у | у | NS | у | n | у | NS | NS | с |
| Maloney & Harris, 1990 | у | у | NS | n | у | у | у | у | у | | у | у | у | у | у | у | у | NS | NS | с |

^{*} Studies not comparing typical prostheses.
 ^d Although the same patients were evaluated for two types of prostheses, operations were, on average, 4 years apart, so there were differences in many variables.
 ^e Detailed results given for five out of nine prosthesis models.
 ^f First part of study prospective observation, second part retrospective comparison.
 ^g Harris Hip Score only section to have pre- and post-operative scores compared, even though many other sections could have been assessed in this way.
 ^h Only loosening rates given for specific models.
 ⁱ Only failure rate results for specific models.

| | | | | Key cr | iteria | | | | | | | | Ot | her cri | iteria | | | | | |
|---|-----------------|---------------|------|--------|--------|---|---|---|----|----|---|----|----|---------|--------|----|----|----|----|--------|
| Study | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | Rating |
| Markel, et al., 1995 | у | n | n | у | у | у | у | у | у | | у | n | n | NS | n | n | n | n | NS | с |
| McPherson, et al., 1995 | n | у | у | n | n | у | у | у | у | | у | n | n | NS | у | у | n | NS | NS | с |
| Moilanen, et <i>al.,</i> 1996 | n | n | у | n | у | у | у | У | | У | у | у | у | у | у | n | у | у | n | с |
| Moskal, et <i>al.,</i> 1994 | у | n | NS | у | n | у | у | У | | n | у | у | у | NS | у | у | n | n | NS | с |
| Nashed, et <i>al.,</i> 1995 | n | у | n | у | у | у | у | у | у | | n | n | n | NS | у | у | У | NA | NS | с |
| Neumann, <i>et al.,</i> 1996 [*] | NA | NA | у | у | у | у | у | у | | NA | у | у | у | у | n | n | у | NS | NS | В |
| Pierchon, et <i>al.,</i> 1994 [*] | n | n | у | у | n | n | n | n | n | | n | у | n | у | n | n | n | NS | NS | с |
| Pritchett, 1995 | n | n | у | n | n | у | у | n | n | | у | у | n | NS | у | n | у | NA | NS | с |
| Pupparo & Engh, 1989 | n | n | NS | у | у | у | у | n | | NS | у | у | n | NS | n | у | у | NS | NS | с |
| Ranawat, et <i>a</i> l., 1988 [*] | у | у | у | y/n | у | у | у | у | у | | n | у | n | NS | у | у | у | NS | NS | В |
| Rand & Ilstrup, 1983 | n | у | у | n | у | у | у | у | у | | у | у | n | NS | у | n | у | NS | NS | с |
| Riska, 1993 | у | n | n | У | у | у | у | у | NS | | у | n | n | NS | у | n | у | NS | NS | с |
| Ritter & Gioe, 1986 | у | у | NS | у | у | у | у | у | | NS | у | у | у | у | у | n | у | NS | NS | с |
| Ritter, 1995 | n | n | у | у | у | у | у | у | у | | у | У | n | NS | у | n | у | n | NA | с |
| Schreiber, et al., 1993 | у | n | у | у | у | у | у | у | у | | у | у | n | NS | у | n | n | NS | NS | с |
| Schuller & Marti, 1990 | n | n | у | у | у | у | у | у | у | | у | у | n | NS | у | у | n | NS | NS | с |
| Turner, 1994 | n | n | у | n | n | у | у | n | n | | у | у | n | NS | у | n | n | NS | NS | с |
| Visuri, et al., 1994 | n | у | у | у | у | у | у | у | у | | у | у | n | NS | у | n | n | NA | NA | с |
| Walker, et <i>al.,</i> 1995 | NS ⁱ | n | у | n | n | у | у | n | n | | n | у | n | у | у | n | у | NA | NS | с |
| Wilson- MacDonald & Morscher, 1989 | n | n | у | у | n | у | у | у | у | | у | n | n | NS | n | n | у | NS | NS | с |
| Wixson, et al., 1991 | у | n | у | у | у | у | у | у | | NS | n | у | у | у | у | n | у | NS | NS | с |
| Yahiro, et <i>al.,</i> 1995 | Me | l ta-analy | vsis | | | | | | | | | • | • | | | | | | | |
| Zicat, et al., 1995 | у | у | у | n | у | у | у | у | у | | у | у | n | у | у | у | у | NA | NS | с |
| Zichner & Willert, 1992 | n | n | n | n | у | у | у | n | у | | у | у | n | NS | n | n | n | NS | NS | с |

⁵ Studies not comparing typical prostheses. ^j Assignment of patients to different prosthesis described in Marston, et al., 1996¹²⁰ (RCT).

Observational studies – appraisal criteria

Key criteria

1. Method of selection of patients identified. 2. Prosthesis models specified. 3. Results given for specific models. 4. Follow-up period, range/mean specified. 5. Number of patients deceased or lost to follow-up reported or included in analysis. 6. Ages – mean/range. 7. Preoperative diagnoses of reviewed patients specified with percentages/numbers. 8. Clearly defined criteria for measuring outcomes/ quantification of outcomes. for deceased patients. 12. Clinical evaluation independent of operating surgeon. 13. Radiological evaluation independent and blinded to clinical results. 14. Numbers of men/women specified. 15. Weight range/mean specified. 16. Surgical technique/approach specified. 17. Grade/ experience & number of surgeons specified. 18. Type of hospital/centre (general/specialist/ teaching) specified. 19. Unilateral/bilateral results separate. 20. Independence of investigators (vested interest) specified.

An abbreviated form of these criteria is given in a footnote to *Appraisal Tables 3–9.*

continued

Other criteria

9. Valid statistical analysis. 10. Outcome data compared with preoperative data. 11. Data given

| | | | I | Key cr | iteria | | | | | | | | Ot | her cı | riteria | | | | | | |
|-----------------------------------|-----|-------|--------------|---------|--------|-----|----|----|----|----------|---------|--------|-------|--------|---------|----|-----|----|----|----|-------|
| Study | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Ratin |
| Ahnfelt, et al., 1990 | у | у | у | n | n | n | у | | у | n | n | NA | NA | у | n | n | n | у | | NA | с |
| Brady & McCutchen, 1986 | ? | У | У | y/n | NA | у | У | У | n | n | NA | n | n | у | n | у | У | n | n | n | С |
| Carlsson, et al., 1986 | ? | у | у | у | у | у | у | у | ? | NA | n | n | y/nª | n | n | у | у | у | n | n | B/C |
| Carter, et al., 1991 | n | у | у | у | у | n | n | | | | | | | | | | | | | | С |
| Collis, 1988 | у | у | y/n | у | у | n | n | | n | n | n | n | n | n | n | у | у | у | | n | с |
| Dall, et <i>al.,</i> 1988 | у | у | У | у | у | у | у | у | ? | n | n | n | n | у | n | n | n | у | n | n | В |
| Dall, et <i>al.,</i> 1988 | n? | у | У | у | n? | n? | n? | n? | Ab | stract o | of conf | erence | paper | | | | | | | | ? |
| Dall, et <i>al.,</i> 1993 | у | у | У | у | у | у | у | | у | n | n | NS | NS | у | n | n | n | n | | n | В |
| Eftekhar & Tzitzikalakis, 1986 | у | у | У | y/n | у | у | у | у | ? | NA | у | n | n | у | n | у | У | у | n | n | В |
| Eftekhar, I 987ª | n | у | у | у | n | n | n | | | | | | | | | | | | | | с |
| Garcia-Cimbrelo & Munera, 1992 | у | У | У | у | у | у | У | | У | У | n | NS | NS | у | У | У | y/n | у | | у | A |
| Gudmundsson et al., 1985 | у | у | У | у | у | у | У | | NS | n | n | NS | NS | У | n | У | n | у | | n | В |
| Hamilton & Joyce, 1986 | у | у | У | у | у | y/n | У | У | ? | У | n | n | n | У | n | У | У | у | n | n | В |
| Hamilton & Gorczyca, 1995 | ? | у | у | у | у | у | у | у | у | n | n | n | n | у | n | у | У | у | n | n | В |
| Hartofilakidis, et al., 1989 | у | у | У | у | у | у | у | | NS | n | n | n | n | у | n | у | У | У | | n | В |
| Hodgkinson, et al., 1993 | see | e Com | ı parativ | e studi | es | | | | | | | | | | | | | | | | с |
| ohnsson, et al., 1988 | у | у | y/n | n | у | у | у | | у | n | у | NS | NS | у | n | у | n/y | у | | n | с |

APPRAISAL TABLE 3 Observational: cemented – Charnley

Key: 1. Selection of patients. 2. Prosthesis models. 3. Results for models. 4. Follow-up period. 5. Loss to follow-up/deceased. 6. Ages. 7. Preoperative diagnoses. 8. Outcomes clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Radiological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

| | | | I | Key cr | iteria | | | | | | | | Ot | her cı | riteria | | | | | | |
|-------------------------------------|-----|--------------|--------------|-------------|--------|-------|--------|-----|-----|----------|---------|--------|----|--------|---------|----|-----|-----|----|----|--------|
| Study | Т | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Rating |
| Johnston & Crowninshield, 1983 | у | у | у | у | У | n | n | | n | n | n | NS | n | n | n | у | У | n | | n | с |
| Joshi, et <i>al.,</i> 1993 | у | у | у | у | у | у | у | у | у | у | у | n | n | у | y/n | n | y/n | у | n | у | A |
| Karachalios, et <i>al.,</i> 1993 | у | у | У | У | У | n | У | | У | n | n | NS | NS | У | n | У | У | у | | n | с |
| Kavanagh, et <i>al.,</i> 1989 | у | у | У | у | у | у | n | | у | n | n | NS | NS | у | n | у | n | у | | у | с |
| Kobayashi, et <i>al.,</i> 1994a | у | у | У | у | у | у | у | у | у | у | n | n? | у | у | n | у | у | у | n | n | A/B |
| Kobayashi, et <i>al.,</i> 1994b | у | у | У | у | у | у | у | у | у | у | n | n? | у | у | n | у | У | У | n | n | A/B |
| Langlais, et al., 1995 | Me | r chanic: | s of loc | osening | study | – not | apprai | sed | | | | | | | | | | | | | ? |
| Madey, et <i>al.</i> , 1997 | ? | у | У | У | у | у | у | у | у | у | У | n | n | у | NS | у | у | У | n | у | A/B |
| McCoy, et al., 1988 | у | у | у | у | У | у | у | | y/n | n | У | NS | NS | у | у | n | n | У | | n | A/B |
| Neumann, et <i>al.,</i> 1994 | у | у | У | у | у | у | у | | у | n | n | NS | NS | у | n | у | n | у | | у | В |
| Neumann, et <i>al.,</i> 1996 | see | l Comp | l arative | l studie | es | | | | | | | | | | | | | | | | В |
| Nicholson, 1992 | n | у | у | у | n | n | n | | | | | | | | | n | n/y | у | | n | с |
| Older, 1986 | у | у | у | у | у | n | у | | n | n | n | у | NS | n | n | n | у | у | | n | с |
| Older & Butorac, 1992 | у | у | у | У | у | у | у | | У | n | n | NS | NS | У | n | n | n?y | n | | n | В |
| Picault & Michel, 1995 | ? | у | у | y/n | n | n | n | n | Ab | stract o | only | | | | | | | | | | C? |
| Ranawat, et al., 1989 | Co | nferen | ce abst | ract | | | | | | | | | | | | | | | | | ? |
| Rasmussen, et al., 1991 | ? | у | У | y/n | ? | y/n | у | ? | Ab | stract o | only pu | blishe | 1 | | | | | | | | B? |
| Schulte, et al., 1993 | у | у | у | n | у | у | у | | n | n | у | NS | NS | у | n | у | у | у | | у | с |
| Skeie, et al., 1991 | у | у | У | у | у | у | у | | у | n | у | NA | NA | у | n | у | n/y | у | | n | А |
| Solomon, et <i>al.,</i> 1992 | ? | у | У | У | NA? | у | У | У | У | n | NA? | n | n | у | n | n | n | n | n | n | B/C |
| Stauffer, 1982 | у | у | У | У | у | у | у | | n | n | n | NS | NS | у | n | у | n | у | | n | в |
| Sullivan, et <i>al.,</i> 1994 | ? | у | У | У | У | у | у | У | у | n | У | n | n | у | n | у | У | у | n | у | A/B |
| Terayama, 1986 | ? | у | у | y/n | у | у | у | ? | | | | | | | | | | | | | с |
| Thomas & McMinn, 1991 | n | у | у | n | n | n | n | | | | | | | | | | | | | | с |
| Wejkner & Stenport, 1988 | у | у | у | у | У | у | у | | у | n | n | NS | NS | у | n | у | у | y/n | | n | В |
| Welch, et al., 1988 | у | у | У | у | у | у | у | у | n | n | n | n | n | у | n | у | n | n | n | n | B/C |
| Wroblewski, 1986 | у | у | У | У | у | у | у | | у | у | n | NS | NS | у | n | n | n | у | | n | В |
| Wroblewski & Siney, 1993 | n | у | у | у | n | у | у | | n | n | n | NS | NS | у | n | n | n | у | | n | с |

APPRAISAL TABLE 3 contd Observational: cemented – Charnley

 a New data only assessed. ? Doubtful that criterion met; not clear from paper.

Key: I. Selection of patients. 2. Prosthesis models. 3. Results for models. 4. Follow-up period. 5. Loss to follow-up/deceased. 6. Ages. 7. Preoperative diagnoses. 8. Outcomes clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Radiological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

| | | | | Key cr | iteria | | | _ | | | | | Ot | her cı | riteria | | _ | | | _ | |
|----------------------------------|----|--------|---------|--------|---------|-----|-----|---|----|----------|------|----|-----|--------|---------|----|----|----|----|----|-------|
| Study | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Ratin |
| Alsema, et al., 1994 | ? | у | у | у | у | y/n | у | у | у | n | у | n | n | у | n | у | у | ? | n | у | A/B |
| August, et al., 1986 | ? | у | у | у | у | у | у | у | у | n | n | n | n | у | n | у | n | у | n | n | A/B |
| Ballard, et <i>al.,</i> 1994 | ? | у | у | у | у | у | у | у | у | n | у | n | n | у | n | у | у | у | n | у | A/B |
| Bohler, et al., 1994 | у | у | у | у | у | у | у | у | у | у | n | n | n | у | n | у | n | у | n | n | В |
| Bosco, et al., 1993 | ? | у | у | у | у | у | у | у | у | n | n | у | у | у | у | у | у | у | n | n | A/B |
| Bryant, et al., 1991 | ? | у | у | у | у | у | у | у | у | NA | у | n | n | у | n | n | n | у | n | n | В |
| Dorr, et al., 1994 | ? | у | у | У | ? | у | у | ? | ? | ? | NA | n | n | у | n | n | n | у | n | n | с |
| Fowler, et al., 1988 | ? | у | у | у | у | у | у | у | ? | У | n | n | n | у | n | ? | у | у | n | n | В |
| Harris & Penenberg, 1987 | ? | ? | у | у | у | у | y/n | у | ? | n | n | n | n | у | n | n | у | у | n | у | B/C |
| Helfen, et al., 1993 | у | у | у | у | У | у | у | | у | | | | | | | | | | | | ? |
| Hirose, et al., 1995 | ? | у | у | у | у | у | у | у | Ab | stract (| only | | | | | | | | | | В |
| Jantsch, et al., 1991 | ? | у | у | у | у | у | у | у | ? | n | у | n | n | n | n | n | n | ? | n | n | В |
| Karrholm, et <i>al.,</i> 1994 | ? | у | у | у | у | у | у | у | у | NA | n | NA | n | у | n | у | n | у | n | у | A/B |
| Lachiewicz & Rosenstein, 1986 | ? | у | у | у | ? | у | у | у | ? | n | NA | n | n | у | у | у | n | у | n | n | B/C |
| Mohler, et <i>al.,</i> 1995a | | | | | | | | | | | | | | | | | | | | у | ? |
| Nizard, et <i>al.,</i> 1992 | Me | chanic | s of lo | osenin | g study | , | | | | | | | | | | | | | | n | A/B |
| Ohlin & Onsten, 1990 | ? | у | у | ? | у | у | у | у | у | n | у | n | n | у | у | у | n | у | n | n | В |
| Ohlin, 1990 | у | у | у | у | у | у | у | у | у | n | n | n | n | у | у | у | у | у | n | n | В |
| Oishi, et al., 1994 | ? | у | у | у | у | у | у | у | ? | n | y/n | n | n | у | у | у | у | n | n | у | В |
| Papenfus, et al., 1992 | ? | у | у | у | у | у | у | у | ? | у | n | n | n | у | n | ? | ? | у | n | n | B/C |
| Partio, et <i>al.,</i> 1994 | ? | у | у | у | у | у | у | у | у | n | у | у | у | у | у | у | у | у | n | n | А |
| Pearse, et al., 1992 | у | у | у | у | у | у | у | у | n | n | у | n | n | n | n | у | у | у | n | n | B/C |
| Roberts, et al., 1987 | у | у | у | у | у | у | у | у | у | n | у | NA | NA | у | n | у | у | у | n | n | А |
| Rockborn & Olsson, 1993 | ? | у | у | ? | у | у | у | у | ? | n | n? | n | n | у | n | у | n | у | n | у | В |
| Russotti, et al., 1988 | у | у | у | у | у | у | у | у | у | у | NA | n | n/y | у | n | у | n | у | n | n | А |
| Thomas, et <i>al.,</i> 1986 | у | у | у | у | у | у | у | у | у | NA | n | n | n | у | у | у | у | у | n | n | A/B |
| Tompkins, et <i>al.,</i> 1994 | ? | у | у | у | у | у | у | у | у | у | n | n | n | у | у | у | у | у | n | n | A/B |
| Warren, <i>et al.,</i> 1993 | у | у | у | у | у | у | у | у | у | n | у | n | n | у | n | у | у | у | n | n | A/B |

APPRAISAL TABLE 4 Observational: cemented – non-Charnley

Key: I. Selection of patients. 2. Prosthesis models. 3. Results for models. 4. Follow-up period. 5. Loss to follow-up/deceased. 6. Ages. 7. Preoperative diagnoses. 8. Outcome clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Radiological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

? Doubtful that criterion met; not clear from paper.

| | | | | Key cr | iteria | | | | | | | | Ot | her cı | iteria | | | | | | |
|--|----------------|--------|----------------|---------------|--------|---|---|-----|-----|----|-----|----|----|--------|----------------|----|----|----|----|----|--------|
| Study | Т | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Rating |
| Bhamra, et al., 1992 | n | у | у | у | n | n | у | у | | | | | | | | | | | | | с |
| Bourne, et al., 1994 | у | у | у | у | у | у | у | у | у | n | n | n | у | у | n | у | n | у | n | у | A/B |
| Callaghan, et <i>al.,</i> 1992 | у | у | У | У | у | у | У | У | У | у | n | n | n | У | n | у | у | у | n | n | В |
| Cordero-Ampuero, et al., 1994 | ? | у | У | У | У | у | у | У | У | У | n | n | n | у | у | у | у | У | n | n | A/B |
| Cracchiolo, et <i>al.,</i> 1992 | у | у | n? | У | У | у | у | У | ? | У | У | n | n | у | у | у | n | у | n | n | B/C |
| Engh & Massin, 1989 | n | у | у | у | n | у | у | у | ? | n | у | n | n | у | n | n | n | у | n | n | В |
| Engh, et <i>al.,</i> 1990 | ? | у | ? | у | у | у | у | у | у | у | n | n | n | у | у | у | n | у | n | n | В |
| Engh, 1993 | n | у | у | ? | n | n | n | ? | | | | | | | | | | | | | С |
| Engh, 1994 | у ^ь | у | у | Уc | y/n | n | n | у | | | | | | | | | | | | | с |
| Engh, et <i>al.,</i> 1997 ^d | у | у | у | min | у | у | у | у | у | у | у | n | n | у | у | у | n | у | n | n | A/B |
| Haddad, et <i>al.,</i> 1990 | у | у | у | у | ? | у | у | у | у | у | NA | n | у | у | n | у | у | у | n | n | A/B |
| Heekin, et al., 1993 | ? | у | у | у | у | у | у | у | у | у | у | n | n | у | n | у | n | n | n | у | A/B |
| Hellman, et al., 1997 | ? | у | у | у | у | у | у | у | ? | n | NA | n | n | у | n | у | у | n | n | n | В |
| Holman & Tyer, 1992 | у | у | у | ? | NA? | у | у | у | ? | у | NA? | n | n | n | n | у | n | у | n | n | B/C |
| Incavo, et <i>al.,</i> 1993 | ? | у | у | у | NA | у | у | у | у | n | NA | n | n | у | n | n | n | у | n | n | В |
| Jansson & Refior, 1992 | ? | у | У | У | У | у | У | У | n | n | NA | n | n | n | n | n | n | у | n | n | B/C |
| Kienapfel, et al., 1991 | ? | у | ? ^a | у | у | у | у | у | у | у | n | n | n | у | n | у | n | ? | у | n | В |
| Kim & Kim, 1992 | ? | у | у | у | ? | у | у | у | ? | n | NA? | n | n | у | у | у | у | У | n | у | B/C |
| Kim & Kim, 1993 | ? | у | у | у | у | у | у | у | у | ya | NA | n | n | у | ? | у | n | у | n | у | A/B |
| Lachiewicz, 1994 | у | у | у | у | NA | у | у | у | n | у | NA | n | n | у | у | у | у | у | n | n | B/C |
| Learmonth, <i>et al.,</i> 1995 | у | у | У | У | у | у | У | У | У | У | n | n | n | У | n | n | n | у | n | n | A/B |
| Maloney, et al., 1992 | ? | у | у | у | у | n | n | у | | | | | | | | | | | | | С |
| Martell, et al., 1993 | у | у | у | у | у | у | у | у | у | у | n | у | у | у | y ^e | у | у | у | n | n | A |
| Moskal, et al., 1994 | у | у | у | у | у | у | n | у | ? | у | NA | у | у | у | n | у | n | у | n | n | B/C |
| Negre & Henry, 1995 | ? | у | У | у | у | у | у | у | ? | n | n | ? | ? | у | n | ? | n | n | n | n | В |
| Owen, et al., 1994 | ? | у | у | у | у | у | у | у | у | ? | у | n | n | у | n | у | у | У | n | у | A |
| Pellegrini, et al., 1992 | у | у | у | у | у | у | у | у | ? | n | у | у | n | у | n | у | n | У | n | у | В |
| Schmalzried & Harris, 1992 | ? | У | У | У | у | у | у | ? | ? | n | n | n | n | у | n | у | у | У | n | у | В |
| Shaw, et <i>al.,</i> 1992 | у | у | У | у | NA | у | у | у | у | у | NA | n | n | у | n | n | n | n | n | у | В |
| Smith, et al., 1991 (M) | у | у | у | у | у | у | у | y/n | y/n | у | n | у | у | у | у | у | у | у | n | n | B/C |
| Sotereanos, et al., 1995 | у | У | У | У | У | у | у | У | ? | У | ? | n | n | n | n | n | n | n | n | n | В |
| Tang-Kue, 1995 | Ab | stract | only av | ı vailable | | | | | | | | | | | | | | | | | ? |
| Xenos, et al., 1995 | ? | у | у | ? | NA | у | у | у | у | n | NA | n | n | у | n | n | n | у | n | у | В |

APPRAISAL TABLE 5 Observational: cementless - porous-coated

^a Results for two models not disaggregated for clinical scores; ^b One hip only of bilaterals included; ^c Mean only; ^d Longest follow-up of the Engh AML studies – forthcoming $I997; e^{\text{Measured but not stated.}}$ M = Modular component(s)

? Doubtful that criterion met; not clear from paper.

Key: 1. Selection of patients. 2. Prosthesis models. 3. Results for models. 4. Follow-up period. 5. Loss to follow-up/deceased. 6. Ages. 7. Preoperative diagnoses. 8. Outcomes clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Radiological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

| | | | | Key cr | iteria | | | | | | | | Ot | her cı | riteria | | | | | | |
|------------------------------------|---|----|---|--------|--------|---|----|---|-----|--------|----------|-------|----|--------|---------|----|----|----|----|----|--------|
| Study | Т | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Rating |
| Capello, 1994 | ? | у | у | у | у | у | у | у | ? | n | n | n | n | у | n | n | n | n | n | n | с |
| Capello, et al., 1994 | у | у | у | у | у | у | у | у | у | n | n | n | n | у | у | у | n | у | n | n | B/C |
| d'Antonio, et <i>al.,</i> 1992a | ? | у | У | ?Þ | NA | у | у | У | ? | У | NA | у | у | у | у | у | n | у | n | у | A |
| d'Antonio, et <i>al.,</i> 1992b | ? | у | У | У | ? | У | У | у | У | У | ? | n | n | У | У | У | n | n | n | n | A/B |
| Drucker, et al., 1991 | у | у | у | у | у | у | у | у | Fol | low-up | o < 12 i | nonth | S | | | | | | | | с |
| Geesink, 1990 | у | у | У | у | у | у | У | у | у | У | ? | n | у | у | n | у | n | у | n | n | A/B |
| Geesink & Hoernagels, 1995 | ? | У | У | У | У | У | У | у | у | У | NA | n | n | у | у | у | у | у | n | у | A |
| Koch, et al., 1993 | ? | у | у | у | ? | у | у | у | ? | у | | | | | | | | | | | B? |
| Rossi, et al., 1995 | ? | у | у | у | у | у | у | у | у | у | NA | n | n | у | n | у | n | у | n | n | A/B |
| Tonino, et al., 1995 | ? | y. | y | y | ? | y | y. | y | y | y. | n | n | n | y | ?ª | y | n | n | у | n | A/B |

APPRAISAL TABLE 6 Observational: cementless – HA-coated

^a Measured but not specified; ^b Only minimum follow-up period specified.

? Doubtful that criterion met; not clear from paper.

Key: 1. Selection of patients. 2. Prosthesis models. 3. Results for models. 4. Follow-up period. 5. Loss to follow-up/deceased. 6. Ages. 7. Preoperative diagnoses. 8. Outcomes clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Radiological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

| APPRAISAL TABLE 7 | Observational: cementless – uncoated press | -fit |
|--------------------------|--|------|
|--------------------------|--|------|

| | | | I | Key cı | iteria | | | | | | | | Ot | her cı | riteria | | | | | | |
|-----------------------------------|-----|----------|----------|---------|----------------|-------|------|---|---|----|-----|----|----|--------|---------|----|----|----|----|----|--------|
| Study | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | п | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Rating |
| Stems/stems and cu | ıps | | | | | | | | | | | | | | | | | | | | |
| Blaha, et <i>al.</i> , 1994 | ? | у | у | ? | ? ^a | n | n | у | n | n | у | у | у | n | n | n | n | n | n | n | с |
| Duparc & Massin, 1992 | ? | У | У | у | n | у | У | у | У | n | n | n | n | n | n | у | n | n | n | у | B/C |
| Groher, 1983ª | у | у | у | у | n | у | у | у | | | | | | | | | | | | | с |
| lvory, et al., 1992ª | n | у | n | у | n | n | n | n | | | | | | | | | | | | | с |
| Kutschera, et al., 1993 | Ab | stract o | only | | | | | | | | | | | | | | | | | | |
| Ring, 1978 | 3 d | ifferen | t desigi | ns anal | ysed in | aggre | gate | | | | | | | | | | | | | | с |
| Ring, 1987 | у | у | у | у | у | n | n | у | | | | | | | | | | | | | с |
| Seral, et al., 1992 | ? | у | у | у | NA | ? | у | ? | ? | у | NA? | n | n | у | у | у | n | n | n | n | B/C |
| Stockley, et al., 1992 | ? | у | у | у | NA | у | у | у | ? | у | NA | n | n | у | n | у | у | n | n | n | В |
| Cups | | | | | | | | | | | | | | | | | | | | | |
| Glorion, et al., 1994 | у | у | у | у | ? | у | у | у | у | у | NA | n | n | у | у | у | у | у | n | n | A/B |
| Harper, et al., 1995 | ? | у | у | у | у | у | у | у | у | n | n | n | у | n | n | у | у | у | n | у | В |
| Kennedy, 1994 | n | у | у | у | n | n | n | n | | | | | | | | | | | | | с |
| Wilson-MacDonald, et al., 1990 | ? | у | у | у | у | у | у | у | у | n | n | n | n | у | n | n | n | у | n | у | В |

? Doubtful that criterion met; not clear from paper.

Key: 1. Selection of patients. 2. Prosthesis models. 3. Results for models. 4. Follow-up period. 5. Loss to follow-up/deceased. 6. Ages. 7. Preoperative diagnoses. 8. Outcomes clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Radiological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

APPRAISAL TABLE 8 Observational – hybrid

| Study | Key criteria | | | | | | | | | Other criteria | | | | | | | | | | | | |
|------------------------------------|---------------|---|---|---|---|---|---|---|---|----------------|----|----|----|----|----|----|----|----|----|----|-------|--|
| | I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Ratin | |
| Harris & Maloney, 1989 | у | у | ? | У | У | У | У | У | ? | У | n | n | n | У | n | У | у | у | n | у | В | |
| Helfen, et al., 1993 | Abstract only | | | | | | | | | | | | | | | | ? | | | | | |
| Kienapfel, et <i>al.,</i> 1992b | у | у | у | у | у | у | у | у | ? | у | n | n | n | у | n | у | n | у | n | n | в | |
| Mohler, et al., 1995b | у | у | у | у | у | у | у | у | у | у | n | n | n | у | n | у | у | у | n | у | A/B | |
| Pearse, et al., 1992 | ? | у | у | у | у | у | у | у | n | n | n | n | n | n | n | у | у | у | n | n | В | |
| Schmalzried & Harris, 1993 | ? | у | У | у | у | у | у | у | у | n | NA | n | n | у | n | у | n | n | n | у | В | |

s. 3. Re for models. 4. Fo clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Radiological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

APPRAISAL TABLE 9 Observational: cementless – mixed

| Study | | Key criteria | | | | | | | | | Other criteria | | | | | | | | | | | | |
|------------------------------------|---------------------------------------|--------------|---|---|---|---|---|---|---|----|----------------|----|----|----|----|----|----|----|----|----|--------|--|--|
| | Т | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Rating | | |
| Lautiainen, et <i>al.,</i> 1994 | ? | у | У | У | у | у | у | у | ? | n | n | n | n | У | n | У | n | у | n | n | B/C | | |
| Niinimaki, et <i>al.,</i> 1994 | ? | у | у | у | у | у | у | у | ? | n | n | n | n | у | n | у | у | у | n | у | В | | |
| Riska, 1993 | Hybrid and cemented series/uncemented | | | | | | | | | | | | | | | | | | | | | | |
| Roffman & Juhn, 1993 | ? | у | У | ? | ? | n | n | n | | | | | | | | | | | | | С | | |
| Stern, et al., 1992 | ? | у | у | у | n | у | у | у | n | у | n | n | n | у | n | у | n | у | n | n | с | | |

Key: I. Selection of patients. 2. Prosthesis models. 3. Results for models. 4. Follow-up period. 5. Loss to follow-up/deceased. 6. Ages. 7. Preoperative diagnoses. 8. Outcomes clear/quantified. 9. Statistical analysis. 10. Comparison with preoperative data. 11. Data on deceased. 12. Clinical evaluation independent. 13. Rediological evaluation independent. 14. M/F numbers. 15. Weight. 16. Surgical technique. 17. Surgeons' grade, etc. 18. Type of hospital. 19. Bilateral results separate. 20. Independence of investigators.

HTA panel membership

This report was identified as a priority by the Acute Sector Panel.

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